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SELF HELP AND THE EARLY MANAGEMENT OF ACUTE, NON-SPECIFIC LOW BACK PAIN

ANN ROBERTSON

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Abstract

This research investigated whether there might be benefit from encouraging early self management in an episode of non-specific low back – a common and costly condition in the U.K. It aimed to address a lack of research evidence on interventions to improve current, Step 1 of primary care management for back pain. A self help, audio programme, to give information and reassurance about non-specific back pain and skills training in some components of cognitive behavioural pain management, could be used independently at home. Self help could widen access to early, cognitive behavioural based treatment, might offer an inexpensive and practicable means of intervention delivery in busy GP practices and would accord with government policy of encouraging increased self management by NHS patients.

Pilot evaluation: The face validity of two, self help, audio CD programmes for use at home, “Using Relaxation Skills” and “Using Thinking Skills”, was assessed by six primary care patients with non-specific, acute low back pain. Participants in the pilot evaluation expressed some satisfaction with both self help programmes and found them helpful. The audio CD with a focus on progressive muscular relaxation, “Using Relaxation Skills”, was more popular.

Pragmatic randomised controlled trial of self help CD effectiveness: The primary objective was to demonstrate whether using a three week, self help programme at home showed benefits with respect to back pain specific functioning as measured by the Roland and Morris Disability Questionnaire (RDQ). Forty four members of the public with a current episode of back pain lasting between two and nine weeks were randomised to a CD intervention arm or a control arm. Back pain specific functioning, self reported pain intensity and general health and well being in physical and mental domains were assessed at baseline and at one and six months' follow up. Data analysis conducted using a mixed between-within subjects analysis of variance demonstrated significant improvement across all measures over time for all participants. Compared to controls, those using a self help, audio CD showed significantly improved scores on the RDQ at six months [$F = 6.673$, $p = .013$], although the magnitude of the mean group difference was small (partial eta squared = .137). It is concluded that a three week, home based self help programme delivered by audio CD can improve functional outcomes in the short to medium term in early, non-specific low back pain.

Interpretative Phenomenological Analysis (IPA) of self help for back pain: The study aimed to explore possible reasons for the slow uptake by the public of a free, self help CD for early back pain. Nine people with non-specific low back pain were interviewed by email to explore their experiences of using self help for managing pain. An IPA analysis revealed four, major themes: taking control, social comparisons, ongoing learning and “with hindsight”. The findings suggest that turning to self help for back pain may be a developmental process over time, related to the variable course of back pain symptoms. Interviewees wished with hindsight they had been directed towards self management in the initial stages of back pain. At the time of first consulting a GP, they had hoped for a medical “cure”. The findings indicated that slow recruitment into a self help intervention for early low back pain may reflect a lack of perceived need for any intervention in the initial phase of the condition, with implications for the likely uptake of an early, self help intervention.

Key words: acute, non-specific low back pain; self help; Cognitive Behavioural Therapy (CBT), primary care, Interpretative Phenomenological Analysis (IPA)

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1. Chapter One. Setting the scene.

1.1. Introduction

A large proportion of primary care patients who consult with acute, non-specific low back pain may fail to benefit from current “best practice” care. The prognosis for non-specific low back pain is often reported to be good (for example, van Tulder et al., 2002) yet accumulating evidence suggests the natural course of non-specific low back pain may frequently be persistent, fluctuating and recurrent (Henschke et al., 2008; Croft et al., 1998; Horn & Munafo, 1997). This thesis aims to investigate whether initial approaches to managing acute, non-specific low back pain could be improved, with ensuing, improved outcomes.

Von Korff (1999) proposed a stepped care treatment model for managing non-specific low back pain in the U.S.A. and a similar model is implemented in the U.K. National Health Service (NHS). Each ascending level of the stepped care model should apply to a successively smaller proportion of back pain patients. Step 1, at the first consultation, consists of reassurance, advice to stay active and oral analgesia for symptom control, consistent with U.K. clinical guidelines for managing acute, non-specific low back pain. Step 2 in the U.K. might entail referral for NHS physiotherapy or perhaps spinal manipulation for patients who continue to consult with persisting symptoms. A Step 3 intervention, such as referral to a multidisciplinary pain clinic, is reserved for those for whom back pain has developed into a disabling, chronic condition. It is the absence of U.K. research into possible improvements to current Step 1 management, combined with growing evidence that the prognosis for acute back pain may often be poorer than is sometimes assumed, that is the rationale for the thesis research.

About 90% of low back pain seen in primary care is assessed as non-specific. Painful symptoms relate to unidentified, usually presumed mechanical, causes (Koes et al., 2006) and there is no specific pathology associated with the sensation of pain. Typically, an episode of non-specific low back pain is labelled as acute if it has lasted up to six weeks, sub acute if it has lasted between six and 12 weeks and chronic when it has lasted longer than 12 weeks, although temporally defined

categories are potentially misleading. There is not a set time point at which an individual's acute pain turns into chronic pain. Chronic pain is associated with personal distress, functional disability and high economic costs to society (Horn & Munafo, 1997; Maniadakis & Gray, 2000).

No single factor has been found to be a strong determinant of outcome before non-specific low back pain has become chronic and disabling (Hartvigsen et al., 2004). Notwithstanding, recent research has focussed on measuring psychosocial risk factors to try to identify, and subsequently to successfully treat, groups of the sub acute back pain population thought to be at greater risk of developing chronic pain and disability. In a stepped care model of back pain management (von Korff, 1999), such research is directed at improving Step 2 of patient care. Step 2 researchers report remaining optimistic about improving outcomes for sub acute low back pain patients, although to date there has been weak evidence for improved outcomes (van der Windt et al., 2008). There is an absence of U.K. research into improving outcomes for non-specific back pain patients by investigating possible improvements to the current management of acute low back pain at Step 1.

Emerging evidence is starting to challenge the U.K. model of assess, advise and wait at Step 1, particularly with regard to psychological and behavioural factors that may fluctuate in the early weeks and that may influence outcomes (Wand et al., 2004; Sieben et al. 2002). Hence there is the possibility that Step 1 interventions, to address psychosocial prognostic factors before they become stable and perhaps maladaptive, could have the potential to reduce the proportion of patients progressing from Step 1 to Steps 2 and 3. A single study that has investigated improving existing treatment at Step 1 - with a minimal, psychosocial intervention delivered by GPs in The Netherlands - showed no effects, perhaps because GPs in the intervention arm in this study were only moderately successful at identifying patients' individual psychosocial risk factors (Jellema et al., 2005b).

Cognitive Behavioural Therapy (CBT) intervention programmes to enhance self management by chronic pain patients have been shown to be moderately effective (Morley et al., 1999) and may

also be effective in early back pain. No U.K. studies have investigated the effectiveness of CBT based approaches for managing acute, non-specific low back pain, despite some preliminary evidence in its favour from Sweden and the U.S.A. (for example, Linton et al., 2005; Damush et al., 2003).

Self help, to facilitate self care or self management, is currently advocated in National Health Service policy documents. The Scottish NHS Framework for Change document calls for “anticipatory care” and preventative health care to be at the heart of a modernised health service (Scottish Executive, 2005).

The thesis therefore aims to investigate earlier, more active management of acute, non-specific low back pain, which accords with preventative care and increased self management by patients now advocated by NHS policy makers, and particularly an early introduction to CBT based self help for back pain. It is speculated that a CBT based, self help intervention at Step 1 has the potential to enhance individuals' abilities to self manage the common, and often long term, problem of non-specific back pain and could thereby contribute to improving back pain outcomes.

In Scotland, back pain is the fifth most common reason for consulting a family doctor and it is estimated that across the U.K. some 1.6 million back pain patients annually are referred to a NHS specialist (van Tulder et al., 2005; Waddell, 2004). People with back pain may use a range of privately funded therapies, such as private physiotherapy, osteopathy, chiropractic, acupuncture, reflexology, aromatherapy and massage, either as an alternative to or as an addition to NHS care. Privately funded health care for back pain in the U.K. in 1998 was estimated to cost £565 million, with NHS costs totalling £975 million and further costs, arising from back pain related absenteeism and lost productivity, estimated at £5 billion (Maniadakis & Gray, 2000; Waddell, 2004). Recurrent and chronic low back pain have been reported to underlie more than three quarters of lost work days (van Tulder et al., 2005). Estimates of the prevalence of low back pain in the U.K. population vary, however, published figures indicate that the majority of adults will experience low back pain at some time in their lives (van Tulder et al., 2005; Dionne, 1999). While non-specific low back pain is

not life threatening, it is evident that it is a commonly experienced condition and one that has significant, economic costs for society. It is also a condition that can be associated with considerable distress for afflicted individuals and their families, particularly among those individuals – a minority of the total - whose back pain develops into chronic pain and disability (Ohayon & Schatzberg, 2003; Hagen et al., 2006).

Many people will not seek an NHS appointment when they experience an acute episode of non-specific low back pain (Waddell, 2004). It is estimated that up to 80% of those with a current episode of low back pain will choose not to present in the consulting room (Papageorgiou & Rigby, 1991) and research attention is focussed on the people who do consult (Macfarlane et al., 2006). Those consulting in Scotland will encounter differing models of service delivery, depending on the health board region in which they attend (Nic Lochlainn et al., 2008). Clinical approaches should nonetheless all reflect U.K. and European clinical management guidelines (for example, Prodigy, 2005), which are based on a biopsychosocial understanding of non-specific low back pain. The biopsychosocial approach has five, main elements, according to Waddell (2004). These are: physical dysfunction; beliefs about back pain; psychological distress; illness behaviours; and social interactions.

A present lack of good quality evidence relating to acute, non-specific low back pain is acknowledged in a health technology assessment report for the NHS in Scotland (Nic Lochlainn et al., 2008). The report indicates that studies involving patients with non-chronic back pain can be hard to interpret because symptom duration at recruitment and at intervention is often unreported or unclear. Difficulties with interpreting studies with respect to acute back pain patients combine with concerns about the methodological quality of some published trials, notably inadequate or absent randomisation, small sample sizes, lack of reported baseline data and an absence of controls. The report also highlights concerns relating to outcome measures and length of follow up. Variation in outcome measures used in studies precludes pooling the results of different trials. Follow up periods are often short; implementing the results of studies that demonstrate improved outcome measures in the short term may help reduce the number of people declining from acute to

chronic pain, whereas evidence for preventing future, repeated acute episodes would require trials with longer follow up periods (Nic Lochlainn et al., 2008).

The researcher traces a pathway through a very large literature on musculoskeletal pain to support the contention that there is untapped potential to improve Step 1, primary care management of non-specific low back pain. The format and contents of one such, potential intervention – CBT based, self help, audio CDs for home use - are developed and initially evaluated by low back pain patients at a Scottish GP surgery. The barriers to researching and implementing new, evidence based, Step 1 interventions in primary care in Scotland are highlighted. As a result of these barriers, an exploratory trial of the effectiveness of self help, audio CDs for early, non-specific low back pain is carried out in the community and the findings are reported. The argument for a greater focus on Step 1 management in primary care is strengthened by a subsequent, qualitative study to explore when and why back pain sufferers may adopt self help strategies to manage the condition more successfully.

In the following section, the context in which the thesis has been developed is discussed, namely the biopsychosocial model and the advance of Social Cognition Models in mainstream health psychology. Those models' underlying assumption of modifiable social cognitions is linked to CBT before a summary of the place of CBT in pain management. The author's epistemological position is stated, then the way in which the main body of the thesis is organised is outlined.

1.2. Biopsychosocial framework

The biopsychosocial model underpins current training and practice in health psychology and is the framework for this thesis. With its foundations in general system theory, first described by the biologist von Bertalanffy in 1968, the biopsychosocial model expounds the integration of biological, psychological and sociocultural subsystems in the aetiology and maintenance of health and illness. Thus the model advocates a holistic, usually “patient-centred”, view of complex individuals operating as part of multi layered, interconnected subsystems - which may be contrasted with a

more limited, biomedical perspective and a focus on biological disease processes. Engel (1980) is credited with advancing the biopsychosocial model, initially in psychiatry. In the 21st century, the biopsychosocial model underlies the whole endeavour of health psychology, not only research and practice in mainstream health psychology but also critical health psychology (Stam, 2004).

However, it is arguable whether the “biopsychosocial model” is a model beyond the loose sense of a general framework. Stam asserts it is neither a scientific theory nor a model derived from a theory and concludes that the term is a neologism that has: “... a certain rhetorical function that is more important than its purported theoretical contribution to the discipline” (Stam, 2004, p. 20). Other health psychologists, while accepting actual and potential benefits of the biopsychosocial model, have criticised its implementation to date, particularly a failure by practitioners to integrate the subsystems and to specify the relationships between them. Spicer & Chamberlain (1996), for instance, highlight a common neglect of the social subsystem in health psychology research. Similarly, in pain research, Blyth et al. (2007) note how few “psychosocial” interventions for chronic pain in fact address social factors. Cooper et al. (1996) argue that, in practice, health psychologists use the model as a general, explanatory framework in which multiple levels may interact with one another but are still viewed as essentially separate systems that can operate independently.

Mainstream health psychology’s frequent emphasis on lifestyle and individual based interventions has resulted in further criticism of the underlying biopsychosocial model for, in some cases, leading health psychologists to exaggerate people’s control over their individual lifestyles and health choices and, with that, an implicit danger of victim blaming (Jones, 2003).

Stam’s (2004) assertion that the biopsychosocial model is not a model in a traditional, scientific sense is accepted and hereafter this thesis will use the term biopsychosocial framework. It is possible that, in the future, this framework may be developed into a formal model that can specify how the subsystems interconnect, as advocated by Suls & Rothman (2004), or it may be that the framework’s historical linkage to the original general system theory could usefully be loosened to embrace acceptance of conceptually different and non-hierarchical systems that interact with each

other (Malmgren, 2005). In either case, and notwithstanding some of its present problems, the biopsychosocial framework is a valuable construct to guide health psychology research and practice. Most obviously, it has highlighted the importance of recognising multiple factors – biological, psychological, behavioural, social, economic and cultural – that influence health and illness. Public health innovations and biomedical advances have reduced mortality from acute illnesses in the wealthy, developed world; a biopsychosocial framework offers a more appropriate perspective from which to address the causes, maintenance and management of problematic, chronic and recurrent conditions, including back pain, now prevalent in our society (Lyons & Chamberlain, 2006).

1.3. Social Cognition Models in health psychology

The biopsychosocial framework has underpinned the development in health psychology of a range of theoretical models of the ways in which cognitive factors (knowledge, beliefs and attitudes), which individuals acquire within social environments, may influence health behaviours. Health behaviours may be thought of as health harming behaviours, such as cigarette smoking, health protective behaviours, such as condom use, and health enhancing behaviours, such as following current recommendations for regular, physical exercise. Some determinants of these health behaviours are external, such as income and Government legislation, while others, such as cognitions and personality traits, are characteristics of individuals. The rationale for mainstream health psychology's prominent interest in Social Cognition Models (SCMs) is that the individual's social cognitions are believed to be an important predictor of his or her health behaviours, and one which may mediate other determinants, for example, that person's socio-economic status (Conner & Norman, 2005). Importantly, social cognitions are also considered to be variables intrinsic to individuals that are potentially amenable to intervention and change, more readily so than, for example, personality traits.

Perhaps the best known and most widely used SCM is the Health Belief Model (Becker, 1974), despite numerous criticisms of its limitations (Abraham & Sheeran, 2005). It is one of several,

widely published SCMs that aim to predict health behaviours and outcomes. Models of this type include the Theory of Reasoned Action, the Theory of Planned Behaviour (Ajzen & Fishbein, 1980; Ajzen, 1991) and Social Cognitive Theory (Bandura, 1982). Other SCMs have been developed with the aim of increasing understanding of people's health behaviours by investigating their illness representations, their threat appraisals and the types of coping strategies they employ. Notable in this category is Leventhal's Self-Regulation Model (Leventhal et al., 1984). Forming a third type of SCM are the dynamic models that examine the process, or stages, of behaviour change and maintenance, such as the Transtheoretical Model of Change (Prochaska & Di Clemente, 1984) and the Health Action Process Model (Schwarzer & Fuchs, 1995).

In addition, some SCM researchers have chosen to focus on specific variables to be targeted by interventions if attempts to alter health behaviours are to be more successful, in particular, how someone who has formed an intention to change a health behaviour then translates his or her intention into action (for example, implementation intentions; Gollwitzer, 1993). For detailed accounts of all the SCMs, see Conner & Norman (2005).

Many SCMs have been revised since their inception such that, despite differences between them, considerable overlaps now exist in the constructs (if not always the labels for these constructs) employed across the various models. Notably, the constructs of self efficacy and behavioural intention have emerged as two, key factors influencing health behaviours and these constructs have now been incorporated into several of the revised SCMs. Self efficacy relates to individuals' self evaluations of their own capabilities and their personal ability to control whether or not they can achieve a particular outcome. Self efficacy is considered to be domain specific, with an individual's self efficacy beliefs varying with respect to different types of behaviour and different circumstances. Domain specific self efficacy appraisals may be modified, for example, through CBT, through personal experiences of mastery and through vicarious learning from observing others who execute the desired behaviours successfully (Bandura, 1977).

SCMs have in common an emphasis on conscious, usually rational, cognitive processes. For a brief review of recent research into dual process models, which endeavour also to include unconscious or automatic cognitive processing in the models, see Norman & Connor (2005).

In the 1990's, theorists representing some of the major SCMs agreed to meet to clarify if and how their models overlapped and whether elements from the different models could in practice be integrated and so produce a single, parsimonious SCM for health behaviour research (Fishbein et al., 1992). The theorists' meeting resulted in a consensus statement in which the participants identified eight variables that they consider could account for most of the variance in any given, deliberate health behaviour (Fishbein et al., 2001). The first three determinants identified in the consensus statement are: intention; environmental constraints; and skills. These variables are viewed as necessary and sufficient for a particular behaviour to occur or not to occur. The other five are: anticipated outcomes, or attitude; norms; self standards; emotion; and self efficacy. These last five variables are thought principally to influence the strength and direction of intention, although it is suggested they could also exert a direct influence on health behaviours (Fishbein et al., 1992). The eight social cognitive variables proposed for an integrated SCM are given in Box 1.

Box 1. Social cognitive variables underlying deliberate health behaviours.

Adapted from Fishbein et al., 2001.

1. a strong, positive intention or commitment to perform the behaviour
2. no environmental constraints to prevent the behaviour
3. the necessary skills to perform that behaviour
4. believes that the advantages (or benefits, or anticipated outcomes) of performing the behaviour are greater than the disadvantages
5. perceives greater normative (social) pressure for the behaviour than against it
6. perceives the behaviour to be more consistent than inconsistent with self image and that doing it would not violate personal standards
7. has a more positive than negative, emotional reaction to performing the behaviour
8. perceives self efficacy (capability, control) to execute the behaviour

The integrated SCM is not universally accepted. Bandura, for example, the author of Social Cognitive Theory (1982), whose close association with the key construct of self efficacy has made him a highly influential contributor to SCMs, advocates concentrating on the development of an existing SCM to advance health behaviour theory in preference to trying to combine aspects of competing models (Fishbein et al., 2001). Others, for example, Leventhal et al. (2007), advocate working towards developing a comprehensive, process based, social cognitive behavioural theory:

“Given the lack of specificity of behavioral theories, our belief is that they are best treated as complementary views of behavioral processes rather than as competitors.” (Leventhal et al., 2007, p. 382)

The integrated model from the theorists' consensus statement is in need of further empirical research to test it. As yet, it can not specify the relationships between the eight variables it includes, nor does it directly address the important question of implementing behavioural intentions. Nonetheless, the integrated SCM model is accepted as the most parsimonious of the SCMs and variables from the theorists' consensus statement inform the thesis.

It is noteworthy that while SCMs and health behaviours are staples of mainstream health psychology, the assumption that modifiable social cognitions may offer targets for interventions is shared by clinical psychology. Clinical psychologists' principal treatment for depression, supported by a good evidence base, is CBT (Hollon & DeRubeis, 2004). CBT is a therapeutic approach that aims to identify, challenge and modify maladaptive information processing and unhelpful or mistaken beliefs that may underlie a psychological disorder or be contributing to maintaining behavioural difficulties. The use of CBT has expanded rapidly. It is now employed to try to understand and treat a range of disorders in addition to depression, including anxiety, schizophrenia, post traumatic stress disorder, addiction disorders and problematic anger, as well as being used to promote better self management for such conditions as diabetes and chronic headaches (Leahy, 2004; Greenhut, 2007). The role of CBT in managing pain will be reviewed briefly in the next section.

1.4. Cognitive Behavioural Therapy (CBT) for pain management

A cognitive behavioural treatment approach to managing pain acknowledges the place of factors that are related to the physical body, for example, individual neurophysiology, biological disease processes and trauma – present or past – in combination with psychosocial and behavioural factors (Turk & Flor, 2006). The subjective experience of pain and attendant pain behaviours are

therefore understood to be the outcomes of a complex interplay of multiple factors. The transduction, transmission and modulation of sensory inputs are influenced by an individual's genetic make-up, idiosyncratic learning history, cognitive appraisals, personal beliefs and expectations, current physiological state and mood, and by the social environment in which the individual is interacting.

Multidisciplinary pain management programmes using a cognitive behavioural approach, as in specialist pain management clinics, focus on helping patients with persistent pain, distress and disability to foster increased self efficacy, resourcefulness and some degree of active control over how they manage their pain and the multiple problems that may arise from it. See Box 2. Full descriptions of such treatment programmes are available elsewhere, for example, see Turk (1997) and Turk et al. (1983).

Box 2. Structure of cognitive behavioural treatment for pain patients.

Adapted from: “The cognitive behavioural approach to pain management”, Turk & Flor (2006).

- Initial assessment (continues throughout programme)
- Mutually agreed reconceptualisation of patient's views of pain
- Skills acquisition
- Skills consolidation
- Maintenance, generalisation and relapse prevention
- Follow up sessions

The CBT component of multidisciplinary rehabilitation is a collaborative, problem solving endeavour that particularly attends to the relationships between thoughts, feelings, behaviour and

physiology and attempts to help the pain patient develop a range of skills for coping with living with pain. The psychologist's role is considered to be that of an educator and coach, working in tandem with the client and perhaps also with others who are close to the client. Typically, the CBT component will cover re-conceptualisation of the pain sufferer's views of pain, a process of cognitive restructuring during which negative and maladaptive thoughts, feelings and expectations are identified and challenged. Skills acquisition would normally include learning structured, problem solving skills (Shaw et al., 2001); muscle relaxation and alternative relaxation techniques (Turk et al., 1983); attention diversion and distraction techniques (Eccleston & Crombez, 1999); learning the importance of undertaking physical exercise and of activity pacing; assertiveness training; and "fear avoidance" desensitisation through systematic exposure (which may be both real and imaginal) to feared activities (Vlaeyen et al., 2001).

In all of this, the emphasis is on education and on guided "experimenting", that is, on generating alternatives to current, unhelpful practices, weighing their advantages and disadvantages, trying them out and evaluating them. With practice, clients are helped to build up a personal resource of multiple, cognitive and behavioural skills that helps them to live fuller, more satisfying lives despite ongoing pain.

The effectiveness of cognitive behavioural approaches to chronic pain management has been reported in a raft of studies, covering a range of age groups and diverse pain conditions. These conditions include low back pain (for example, Basler et al., 1997). In a meta-analysis by Morley et al. (1999), which focused on randomised controlled trials of CBT and behaviour therapy for chronic pain in adults, significant effect sizes were reported for mood improvement, cognitive coping, activity and pain reduction compared with control conditions. The review by Morley et al. (1999) included 25 trials suitable for meta analysis. The reported effect sizes were statistically significant but not large (median effect size = 0.42 for treatment versus median effect size = 0.33 for controls). Clinically, the effectiveness of CBT treatments for chronic pain is considered to be moderate.

Clinical significance, in addition to statistical significance, is of importance in evaluating interventions. A large sample size may achieve statistical significance even when the magnitude of the intervention effect is very small. Clinical significance is a judgement, however, and one that may be based on a range of factors in addition to the magnitude of a statistically significant treatment effect, such as the prevalence, risks and costs associated with the condition being treated, the costs and resource implications of implementing the intervention and the level of risk associated with any side effects of the intervention (Simon, 2006). Further, an effect size is a measure without units, calculated by combining different studies' reported improvements due to a treatment and dividing them by the standard deviation to give a standardised mean difference. Without knowing how the standard deviation corresponds to the scale of the original outcome measure, it is difficult accurately to interpret the importance of the reported effect. A widely accepted rule of thumb is that proposed by Cohen (1988), who suggests .01 may be considered a small effect size, .06 a moderate effect size and .14 a large effect size. These statistical and clinical considerations may explain why the reported effect sizes for CBT and behaviour therapy for disabled, chronic pain patients – whose condition is associated with high personal distress and high costs to society and whose therapy is not thought to be associated with dangerous side effects – are widely accepted as being of moderate clinical significance.

Despite a large literature on chronic pain and its treatment using CBT, important questions remain unanswered, including exactly which aspects of multifaceted, cognitive behavioural packages account for their observed efficacy (Turk & Flor, 2006). Interaction effects between individuals and types of treatment also remain poorly understood (van Tulder et al., 2003). Further, in face to face therapy, the quality of the “therapeutic alliance” itself may be a significant factor (Turk & Flor, 2006). Hence, while it may be stated with some confidence that cognitive behavioural packages for treating chronic pain are moderately effective, researchers to date have not successfully untangled exactly what works for whom. With psychological approaches to treatment, as with other kinds of treatments, motivation and treatment credibility are likely to influence adherence and outcome. A recent study by Goossens et al. (2005) supports the importance of treatment expectation in a

cognitive behavioural intervention for patients with chronic musculoskeletal pain; an individual's initial beliefs about a given pain treatment's efficacy may significantly influence treatment outcome.

More importantly here, the vast majority of studies into CBT approaches for treating pain are concerned only with chronic pain treatment. There is a relative paucity of evidence relating to its potential application to managing painful conditions, including low back pain, before they have developed into long term, distressing and disabling problems. On the one hand, a research focus on chronic pain is understandable given the overwhelming, negative impact persistent pain can have on individuals, their families, their friends and workplace relationships in addition to the economic costs for society of pain related disability (Maniadakis & Gray, 2000). On the other hand, there remains a need also to research earlier interventions that may have the potential to reduce the burden of low back pain in terms of speeding recovery from discrete episodes, reducing recurrences and possibly also diverting some people from a pathway to long term disability. More recently, there has been a shift in research focus from investigating only chronic pain patients to trying to identify and treat sub groups of back pain patients whose symptoms have persisted for some months and who may be at increased risk for developing chronic pain and disability (for example, Brennan et al., 2006). However, to date there has been very little research interest in the potential role of CBT based interventions in the first weeks following the onset of an episode of non-specific low back pain. A series of studies by Linton and colleagues (Linton et al., 2005; Linton & Ryberg, 2001; Linton & Andersson, 2000) has investigated group CBT for acute and sub acute back or neck pain and two further studies (Moore et al., 2000; Damush et al., 2003) investigated programmes designed to enhance self care in sub acute and acute back pain. The programmes were based on CBT. These studies are reported in detail in Chapter Four. There have been no such early, CBT based intervention studies in the U.K. It is this gap in the currently available evidence on improving back pain outcomes by focussing on Step 1 care that is the concern of this thesis.

1.5. Non-invasive treatments for low back pain before it has become chronic

Interventions to reduce the likelihood of repeated low back pain in the future, and perhaps preventing some with the condition from developing persistent pain and disability, may be classified as secondary prevention. Primary prevention generally refers to interventions designed to divert the onset of new back pain among those who are and have always been back pain free. Studies encompassing both secondary and primary prevention interventions have been undertaken although many of these have been criticised on methodological grounds, particularly limited power to detect intervention effects because of small sample sizes, short follow up periods and low, or unreported, intervention adherence by participants (Linton & van Tulder, 2001).

Twenty seven randomised controlled trials of heterogeneous, prevention interventions for low back pain were included in a systematic review by Linton & van Tulder (2001). Their findings included evidence to support the effectiveness of exercising as a preventative measure along with strong evidence that both lumbar supports and back schools were ineffective. Back schools vary in the exact programmes they offer but their programmes are based on providing education about the back's anatomy and function and teaching isometric – involving muscular contraction against resistance – exercises.

A larger body of investigations is available into a variety of treatments for current, non-chronic low back pain. Consequently, several systematic reviews to evaluate treatment interventions have been published since the mid-1990s. A list of identified systematic reviews into non-invasive treatments for low back pain, before it has become established and associated with on-going disability, is given in Table 1. The strength of the systematic review evidence overall is low. While individual reviews are of high quality, for example, several are Cochrane reviews, the numbers of studies and participants are small and statistical pooling of results was rarely possible due to trial heterogeneity. For example, van Tulder et al. (2000b) identified a total of four randomised controlled trials in their Cochrane systematic review of the treatment effectiveness of back schools. The authors reported limited evidence for treatment benefit from back schools. Compared with no treatment, there was limited support for faster recovery and reduced sick leave in the short term;

no significant differences were found compared to physiotherapy; and outcomes were worse in terms of pain and work absence compared to McKenzie exercises, a type of specific exercise programme that usually also contains an educational element to emphasise undertaking self care.

The heterogeneity of the reviewed studies' populations, interventions and outcome measures resulted in few meta analyses. Many of the systematic reviews reported no differences or inconsistent findings. Notable exceptions are the systematic reviews of advice to stay active versus advice to stay in bed, which found that advice to stay active had significant benefits in terms of faster recovery times, reduced pain and disability and reduced work absence (for example, Waddell et al., 1997).

Table 1. Systematic reviews of evidence for effectiveness of non-invasive treatments for non-chronic low back pain.

Authors	Treatment for low back pain	Comparison	Number of trials reviewed
van der Heijden et al., 1995	traction	placebo; other treatment	2; 2
van Tulder et al., 1997	analgesics	*NSAIDs	3
van Tulder et al., 2000a	behavioral therapy	usual care	1
Waddell et al., 1997	advice to stay active	bed rest; usual care	2; 7
van Tulder et al., 2006	back exercises	no treatment; other treatment	4; 8
van Tulder et al., 2000b	back schools	no treatment; other treatment	2; 2
Hagen et al., 2000	bed rest	advice to stay active; exercises; long versus short bed rest	4; 2; 2
van Tulder et al., 2000c	*NSAIDs	placebo; other drugs; paracetamol	9; 6; 3
Karjalainen et al., 2001 (update: Karjalainen et al., 2003)	multidisciplinary treatment	usual care	2 (2)
Furlan et al., 2002	massage	spinal manipulation	1
van Tulder et al., 2003	muscle relaxants	placebo	11
Assendelft et al., 2003	spinal manipulation	sham; usual care; other treatments	1; 3; 14
Hilde et al., 2003	advice to stay active	bed rest	4

*NSAIDs = non steroidal anti-inflammatory drugs

It can be seen from Table 1 that there are no systematic reviews specifically of early treatment using CBT, although one review evaluated multidisciplinary approaches and one review evaluated behavioural therapy. The Cochrane review by Karjalainen et al. (2001) included only two randomised controlled trials of multidisciplinary treatments that included visits to the workplace. They reported weak evidence of faster return to work and fewer work absences versus usual care.

A single randomised controlled trial on acute low back pain was included in the Cochrane review of behavioural therapy versus usual care (van Tulder et al., 1997). Usual care included taking oral analgesic drugs. The trial found limited evidence both for decreased pain and for reduced, self reported impairment.

Spinal manipulation may confer short term benefit in reducing pain levels but there is no evidence for its long term effectiveness (Assendelft et al., 2003). A subsequently published trial (U.K. BEAM, 2004) favoured the addition of spinal manipulation to GP care for patients whose pain had persisted for six weeks or more whereas a later Australian study, restricted to back pain of less than six weeks' duration, did not (Hancock et al., 2007). Hancock et al. (2007) reported spinal manipulation, with or without a NSAID (diclofenac), conferred no benefit for speed of recovery from an acute episode.

Acupuncture would be considered an invasive treatment. A systematic review of acupuncture and dry needling to treat low back pain included three trials of its use in the early months of back pain (Furlan et al. 2005). No conclusions could be drawn from the available, poor quality evidence.

The most recent review to summarise evidence for non-pharmacological treatments concluded that superficial heat could be helpful for non-specific low back pain in the first four weeks. For pain lasting longer than four weeks, it found evidence for moderate effectiveness of spinal manipulation, exercising, interdisciplinary rehabilitation programmes and of CBT (Chou et al., 2007).

It has been suggested that taking account of the important role of psychosocial factors in how people appraise and respond to pain much earlier on in their experience of pain could benefit low back pain sufferers (van Tulder et al., 2003). In theory, the application of some of the techniques and skills learnt through CBT, currently used quite successfully with pain clinic patients already suffering from chronic pain, could be brought forward. The aim then would be to enhance people's adaptive coping repertoires in the first stages of low back pain and to challenge any developing, maladaptive beliefs, expectations and behaviours before they became entrenched over time. In

practice, adopting a more active approach to the very early management of low back pain would require to be shown to be both efficacious and cost effective. At the moment, international guidelines for early, low back pain management largely favour an initial “watch and wait” approach, paired with advice to stay active and to take analgesics, which is based on the assumption of a good prognosis for the majority of non-specific low back pain patients. Current guidelines for caring for patients in the early stages of a low back pain episode and the research evidence on prognosis will be addressed in Chapter Three.

1.6. Ontology, epistemology and methodology

The biopsychosocial framework is congruent with this author's ontological and epistemological position, which may be outlined as a broadly realist ontology that accepts that an objective world exists independent of our perceptions and interpretations of it while embracing individual subjectivity in constructing those perceptions and interpretations. Researching these different domains requires different methodologies and this thesis reports both quantitative data - on the effectiveness of a self help, audio CD intervention for early non-specific back pain - and qualitative data - exploring back pain sufferers' experiences of the role of self help in managing their condition. Using a mixed design is discussed and justified in Chapter Seven.

1.6.1. Thesis structure

The thesis is structured as follows: Chapter Two defines self help and considers some advantages and disadvantages of self help for health conditions, including back pain. It highlights the current emphasis on self care and on preventative care in NHS policy documents and highlights the current absence of evidence on self help interventions for early, non-specific low back pain in the U.K. Chapter Three reviews how low back pain is defined in the literature and some possible problems in this area in order to clarify the definitions of terms used in this thesis. The literature on low back pain epidemiology is then reviewed and current guidelines on how to manage low back pain are described. The focus of Chapter Four will be narrowed to consider psychosocial treatment interventions for non-chronic low back pain, including the small number of studies to date using

cognitive behavioural based interventions for early low back pain, including two programmes specifically devised to promote self management in early, non-specific back pain. Subsequent chapters report three studies undertaken for this thesis: a pilot evaluation of new, CBT based, self help intervention material for early low back pain (Chapter Five); an exploratory investigation into the effectiveness of self help, audio CDs for early back pain in the community (Chapter Six); a qualitative study of users' experiences with self help for managing low back pain (Chapter Seven); and, finally, a discussion chapter (Chapter Eight) which attempts to draw together what the findings of these new studies may add to what is already known.

1.7. Summary of Chapter One

- The rationale for the thesis is the un-researched potential to improve outcomes for the common and costly condition of non-specific low back pain by seeking improvements to Step 1 of stepped care management
- The thesis advocates more active, self help approaches in the initial stages of non-specific low back pain, in line with NHS policy frameworks for greater patient self care
- The thesis is developed in the context of a biopsychosocial framework and acceptance of the assumption of modifiable social cognitions, common to Social Cognition Models in health psychology and to Cognitive Behavioural Therapy (CBT)
- There is a body of evidence to support the moderate effectiveness of cognitive behavioural treatment approaches for chronic pain, including low back pain
- Theoretically, it may be helpful to bring forward the use of CBT techniques and skills to enhance self managing low back pain when it is in the early stages

- There is an absence of U.K. research evidence on the efficacy (or cost effectiveness) of CBT based, self help approaches to managing non-specific low back pain in its early stages

2. Chapter Two. Self help.

2.1. Introduction

This chapter considers self help in health care – what it is, some of the advantages and disadvantages of self help and the increasing importance being placed both on self management by patients and on preventative, "anticipatory" care in the U.K.'s health services in the 21st century. The possible role for, and impact of the timing of, self help programmes to enhance self management of back related problems is considered.

2.2. What is self help?

Self help may be broadly defined as any action taken by an individual to facilitate self care. Health related self care – or self management - can range from everyday actions to self diagnose and self treat, such as taking painkillers bought from a chemist to treat a self diagnosed tension headache, to installing home adaptations for a person with disabilities, to acquiring and employing considerable, personal expertise about living with a complex, chronic disease, such as diabetes. The Department of Health (DoH) suggests a very wide definition of health related self care. According to the DoH, self care includes all of the actions people take for themselves and for other people in their lives to:

"... stay fit and maintain good physical and mental health; meet social and psychological needs, prevent illness or accidents; care for minor ailments and long term conditions; and maintain health and well being after an acute illness or discharge from hospital." (2005a, p.1)

Self help is also a commercial concern. In developed nations, there is a burgeoning corpus of published self help titles, covering a vast range of mental health problems, interpersonal relationships and other topics. According to Rosen (1987; 1993), more than 95% of commercial self help books are published without documented research to support their effectiveness. Nonetheless, their popularity among book buyers suggests self help is of interest to members of the public; there is a commercial market for self help materials even if it is not clear exactly which

individuals or groups within society are buying them nor how beneficial they prove to be. Many of the commercial, audio materials are varieties of relaxation or meditation. Autobiographies and films, not primarily intended as nor marketed as self help materials, may also be used by individuals as sources of self help information (Norcross et al., 2003). Media based formats for purveying self help advice and information include videotapes, audio tapes and CDs, digital television channels and the Internet.

Williams (2003) states:

"However delivered, self help materials aim to increase the user's knowledge about a particular problem and also to equip them with skills to better self assess and manage their difficulties." (p.134)

The World Internet Statistics (2007) estimate that over a billion people in more than 170 countries now regularly access the Internet. The Internet is becoming an increasingly popular resource for finding health information and advice and for buying medications and health related products on-line. Health websites' contents are unregulated and may be of highly variable quality. This has led to concerns about the factual accuracy and trustworthiness of some of the health information and products available on-line and to concerns about Internet users' ability to discriminate between the dependability of different health related sites (Norcross et al., 2003). There is some qualitative research evidence suggesting that accessing several resources may engender confusion among members of the public. McIntosh & Shaw (2003) conducted focus groups with 37 back pain patients in the U.K. and found that, in seeking information from a range of different sources, participants encountered conflicting information and found it difficult to know which information should be believed.

Information available about low back pain from the Internet was evaluated by U.K. researchers who used a scoring system to rate general quality and the low back pain content of 60 websites (Butler & Foster, 2003). Most of the sites surveyed were judged to be of poor quality and with contents that did not reflect current, evidence based information about low back pain and its

management. The survey authors concluded that health professionals should not advise their low back pain patients to use the Internet as a source of information and advice about back pain except where the contents of particular sites were known by them to be evidence based.

In addition to health information - accurate or otherwise - and items for sale, the Internet offers the possibility of "virtual", self help support groups. Internet based support groups range from membership of reputable charities that host authoritative, moderated sites, such as BackCare (<http://www.backcare.org.uk>), to unregulated groups set up and run by members of the public who share an interest in a particular topic. For instance, on-line "pro-ana" groups are used by individuals who are interested in adopting, or who wish to maintain, anorexic eating behaviours. Informal self help groups have traditionally been organised locally, with face to face meetings. Whether in a traditional format or hosted on the Internet, self help groups have in common that they are set up to address particular situations or problems shared by their members. Self help groups aim to provide social support and education and to encourage members' feelings of confidence in their abilities to cope with their difficulties, that is, to enhance their members' self efficacy beliefs with respect to self managing their situations (Kurtz, 1997).

2.2.1. Supported self help

Participating in informal, social groups for education and support, reading one of the plethora of commercially available self help books or gleaning health related information from the Internet are examples of unsupported self help. Unsupported self help is carried out independently of any health care professional. Supported self help, which also aims to foster knowledge and skills required for better self management of perceived difficulties, would entail either direct or indirect input from a health professional (Williams, 2001). As information and advice from unsupported self help in its various forms may be conflicting, confusing and not based on reliable evidence, an advantage of professionally supported self help is that it should be able to offer people consistent and trustworthy information and advice for self care.

Government policies now reflect a commitment to increasing self care among NHS patients. Implementing such policies is more advanced in England than in Scotland. For example, in England there has been major, financial investment in the Expert Patient Programme (EPP), in which groups of patients who are living with the same chronic illness take part in a programme of structured sessions of training in health related, self management skills. The EPP groups are led by professionally trained, lay volunteers who also have the same chronic illness. These lay led, self help programmes, implemented with training and support from NHS health professionals, purport to be designed to "empower" patients (DoH, 2005a). Other initiatives in England that similarly aim to empower patients to look after themselves more effectively are condition specific programmes, such as DAFNE, which was set up to educate and support patients living with Type 1 diabetes (www.dafne.uk.com). While much of the government emphasis has been and remains on enhancing patients' abilities to self manage chronic health conditions, enhancing self care has potential application across a broad spectrum of health related complaints. It is estimated that 40% of GP time is used for consultations for minor ailments, often with accompanying social or emotional problems; given appropriate support for self help, according to the DoH (2005a), many of these ailments could be managed by patients themselves, with potentially significant implications for reducing demands on NHS resources.

In the view of Williams, who has pioneered CBT based, self help programmes for depression, anxiety and bulimia, supported self help interventions are particularly valuable where skills training is an important facet of successful treatment or management (Williams, 2003). Similarly, the DoH recognises that members of the general public require knowledge and skills if they are to be effective self carers in health matters. Such skills may include: problem solving; planning and implementing those plans; controlling symptoms; being able to access a variety of reliable resources for support; and developing effective partnerships with health care providers (DoH, 2005a). Self help intervention programmes - often CBT based programmes - which teach such skills are unlikely to be suitable for everyone; capacity to self care may be undermined by a range of factors, such as cultural attitudes, poverty, poor social support and a variety of individual characteristics, including poor literacy, limited cognitive ability and low motivation (DoH, 2005a).

Being unsure of one's knowledge and understanding is likely to be a barrier to health related self care. The most socio-economically deprived in the population and very elderly people, both groups more likely to report poorer health, less satisfaction and less perceived control of their lives, report feeling less confident and being less active about pursuing self help for health care. Ethnic minorities, while not reporting worse health, are also found to report being unsure about what health related self management entails and being less likely to engage with self help (DoH, 2005b).

In a survey of public attitudes to self care in England, time and money constraints were the most frequently cited barriers to pursuing self help and to increasing health related self management behaviours. The report's authors speculate these could also serve as "excuses" to mask a lack of motivation although it is unclear why they do so beyond this reflecting their opinion. They write that citing financial hardship and lack of time as reasons for not carrying out health related self care may serve as "excuses":

"... given that self care does not necessarily take more time and money." (DoH, 2005b, p. 4)

The survey found that the most trusted and the most favoured source of information and support to help people assume more responsibility for their own health and well being was the family doctor, followed by information and support from social networks at home and at work. In addition, pharmacists, the Internet, local support groups and the NHS Direct telephone service were cited as possible, potentially useful means to access health education, advice and support for self care. However, although GPs were the preferred resource for increasing health related self management, GPs were not perceived to be providing much by way of information nor encouragement for greater self care. This finding is consistent with a subsequent interview survey of health professionals in England, which included GP participants. It found that NHS health practitioners' awareness of self help resources and patient organisations was low (DoH, 2006). The authors of the 2006 survey reported:

"There appears to be a need for more support for teams working in General Practice and urgent care settings to develop coherent policies and protocols on self care support." (p. 35)

The survey findings are also consistent with earlier, focus group findings from England, specifically relating to low back pain. Focus group participants with low back pain reported that their doctors had given them little or no information about their condition and any relevant services that might be available to them, although these participants claimed to be keen to self manage their back pain and reported frustration with their lack of knowledge to do so (McIntosh & Shaw, 2003). It therefore appears there may be a mismatch between current, government advocacy of self help, some patients' self reported willingness to self manage health matters with support from their GP and the self help resources for back pain currently available from NHS GP practices.

2.3. Anticipatory care

NHS services are organised slightly differently north of the border. A report on the future of the NHS in Scotland cites growing evidence of benefits to be accrued from encouraging self care by patients in terms of improving both clinical and quality of life outcomes, including evidence of improved outcomes in the management of specific symptoms such as pain (Scottish Executive, 2005). In addition, self care is reported to be associated with increased levels of self reported patient satisfaction as well as significant reductions in patients' use of NHS primary care and hospital services. The National Framework for Service Change policy document (Scottish Executive, 2005) states that NHS Scotland needs to change from a service that was designed primarily to deal with acute, medical episodes to a service that promotes preventative health care and provides continuous support for self care by people living with chronic health conditions. It describes these changes as moving from a reactive model of health care to an anticipatory model of health care. The document calls for preventative and anticipatory care to become the key components of a modernised, Scottish health care service:

"The delivery of community based, co-ordinated, anticipatory care with the patient as a partner in providing care is at the heart of our proposals." (2005, p. 238)

Such a shift in the model of service provision by NHS Scotland suggests a different approach to managing the common and costly condition of non-specific low back pain may be timely. Current practice in primary care combines a "watch and wait" approach to non-specific low back pain, based on assumptions of good prognoses for the majority of patients, followed by reactive care for those who decline into chronic disability. An approach in which all early, non-specific low back pain patients were encouraged by the GP to develop self care knowledge and skills, to prevent the condition from deteriorating and perhaps to divert some from chronic pain and disability, would accord more closely with "anticipatory care with the patient as a partner".

2.4. Self help interventions based on CBT

Self help interventions based on education and skills learned from CBT approaches may be considered a means to help some patients become more effective partners in their own health care. An advantage of using self help programmes based on CBT is that they can help widen access to CBT treatments, which is currently often limited to face to face, individual or group CBT sessions delivered by NHS clinical psychologists or trained CBT therapists. Clinical psychology resources are scarce in many areas of the NHS and waiting lists may be long. Self help programmes offer the prospect of evidence based CBT treatments becoming more readily available to a wider range of NHS patients.

Self help interventions utilising CBT may be delivered individually or through group programmes and delivery may be with or without face to face contact with a programme leader. For instance, self help programmes may be delivered on the Internet (Spek et al., 2007; Litz et al., 2007). Some self help programmes are supported by minimal, face to face contact with a professional psychologist (for example, Moore et al., 2000) or with another health care professional (for example, Richards et al., 2002) or they may be led by trained, lay volunteers (von Korff et al., 1998). Some programmes provide a course of self help materials that has been produced by a health professional, which can then be used independently by patients (for example, Williams,

2003). Providing primary care patients with self help materials for independent use offers patients flexibility in when and where they use them and may appeal to people who prefer to work on their difficulties privately or perhaps to avoid a perceived stigma of a referral to clinical or health psychology services. Working successfully through self help materials may itself foster self efficacy and feelings of control over personal health matters (Williams, 2003).

On the other hand, some individuals may prefer to be treated in face to face sessions with a professional CBT therapist or not to engage with any form of CBT based treatment at all. The usefulness of self help programmes is likely to be limited to individuals who are motivated to undertake self help and who have a level of education or cognitive ability that allows them to understand and apply the contents of the self help materials. Usefulness is also likely to be limited to addressing those problems for which there is evidence for effectiveness of CBT (Williams, 2003). Non-adherence to a self help intervention, which is reported to range from 7 – 50% (Cuijpers, 1997; Glasgow & Rosen, 1978), is associated with low motivation and feelings of hopelessness (Whitfield et al., 2001). It may be speculated that unsuccessful, uncompleted, self help programmes derived from CBT could potentially influence future care seeking and treatment adherence, for instance, if such "failed", self help patients later attended a multidisciplinary pain clinic where professionally delivered CBT was an important component of their programme.

Systematic reviews to evaluate self help interventions are dominated by studies that have used CBT based approaches, delivered in various formats and targeting a range of problems, particularly mental health problems. Overall, the reviews of evidence from trials indicate moderate effectiveness for self help interventions while noting that methodological flaws are common, such as highly selective inclusion criteria – more appropriate for efficacy studies than for effectiveness studies (Morley & Williams, 2002) - and study designs in which researchers are rarely blinded to the participants' study group allocation (Williams, 2003). The term "bibliotherapy" has been coined for the use of self help manuals and books. One meta analysis that reviewed 70 bibliotherapy studies found bibliotherapy to be equally effective as therapist led, face to face interventions. In this meta analysis, the estimated mean effect size of 70 diverse studies, which included interventions

such as assertiveness training and treating anxiety, was 0.56 (Marrs, 1995). Earlier, Gould & Clum (1993) reviewed 40 self help studies in their meta analysis and also reported effect sizes for self help interventions that were nearly equivalent to those for treatments delivered by face to face therapy. These authors noted that more rigorously controlled studies showed lower mean effect sizes. They also reported that adherence to the self help programme improved treatment effects. Fear related variables and depression were among the factors found to be potentially modifiable using a self help intervention (Gould & Clum, 1993). For an up-to-date assessment of self help therapies for specific disorders (anxiety disorders; depression; childhood disorders; eating disorders; sexual dysfunctions; insomnia; problem drinking; smoking cessation; dieting and weight loss), see Watkins & Clum (2007). None of the reviewed studies was concerned with CBT based self help for managing living with early, non-specific low back pain.

2.4.1. Promoting self care in managing back pain

Programmes designed to enhance self care may be of value in the management of back pain (Turner, 1996). Evidence for cognitive behavioural self help programmes, facilitated by professionals and by trained, lay leaders, is generally positive for a range of chronic pain patients, including back pain patients (Buenaver et al., 2006). Von Korff et al. (1998) reported that supported, lay led, self help groups were more effective than usual care in promoting positive attitudes towards self management and in reducing back related worries and functional limitations over a one year follow up period. However, the evidence is limited and even more limited on the role of intervention programmes to promote self care before back pain has developed into a chronic problem. Some preliminary, positive findings from programmes that aimed to promote self care among acute and sub acute, non-specific back pain patients have been reported in the U.S.A. (Damush et al., 2003; Moore et al., 2000) and these two studies will be reviewed in detail in Chapter Four of the thesis.

The question of the most advantageous timing of an intervention to encourage self management by back pain patients remains unresolved (Linton, 2002). Some researchers advocate waiting until

non-specific back pain has persisted for six to eight weeks before delivering any "early" intervention (for example, Frank et al., 1996), the rationale for which is that many people may recover spontaneously from non-specific back pain within a few weeks of pain onset (Pengel et al., 2003). The variable course of new or recurrent back pain is likely to make it more challenging for researchers to show significant effects of very early interventions, however, there is no compelling argument against introducing ideas of self care in the initial stages, particularly when recurrent episodes of back pain are common. There is limited, U.K. evidence to suggest some non-specific back pain patients wish to be given greater self help guidance and support from the GP when they consult with an acute episode (McIntosh & Shaw, 2003). Unless contradictory evidence becomes available, an initial, primary care consultation seems an opportune time to encourage the initiation of self management strategies. According to Linton (2002):

"... a primary care setting would appear to be a good point at which to intervene. Patients may be motivated to participate and the health care setting offers a convenient organization from which to administer the program." (p. 331)

Several questions relating to health related self help remain unresolved by the evidence that is currently available, particularly in relation to CBT based self help for non-specific low back pain before it has become chronic and disabling. The available evidence on self help intervention effectiveness and on CBT based programmes to enhance self management of back pain indicates that the potential of an early, self help intervention for non-specific low back pain merits investigation. A CBT based, self help programme is unlikely to suit all primary care patients, however. Further, the ideal timing of such an intervention is contested and the ideal format and content of such an intervention are as yet unknown, as is the likely magnitude of any intervention effect on outcomes in a heterogeneous condition with a variable course.

2.5. Summary of Chapter Two

- Self help, to facilitate self care or self management, may be unsupported or be supported self help that has varying degrees of input by some health practitioner or service

- Current NHS policy in the U.K. advocates increased self management by patients with chronic and acute health conditions, in partnership with health professionals
- Information and advice on health related self help may be confusing, conflicting and lacking an evidence base; the NHS GP seems a favoured source of information and support for increased self management of health conditions, although little of such information and support may currently be available from GP surgeries in the U.K.
- CBT based intervention programmes to enhance self care by chronic pain patients have been shown to be effective and may also be effective in early back pain
- A first, primary care consultation for back pain appears to be an opportune time to initiate self care strategies for managing back pain
- To do this would be in accordance with the Scottish NHS framework for change document that calls for “anticipatory care” and preventative health care to be at the heart of a modernised health service
- Evidence on the best timing, format and content of an early self help intervention for non-specific low back pain is lacking, as is evidence on the likely uptake of and adherence to CBT based, self care programmes by primary care patients

3. Chapter Three. Non-specific low back pain.

3.1. Introduction

This chapter reviews the literature to illustrate how non-specific low back pain is defined, diagnosed and classified as acute, sub acute or chronic. Evidence is presented that non-specific low back pain is a costly and very common problem in developed countries, with an emphasis on U.K. evidence. Research into risk factors is reviewed, in particular, research into psychosocial risk factors for the onset of non-specific low back pain and for the transition from acute to disabling, chronic low back pain. Evidence on the prognosis for acute, non-specific low back pain is presented. Problems with current definitions, methodological issues for low back pain research and problematic issues with the current, dominant research directions are indicated. U.K. guidelines for managing acute, non-specific low back pain are described.

3.2. Defining low back pain

A widely accepted definition of low back pain is pain, stiffness or muscle tension in the lower back, below the costal margin and above the inferior gluteal folds (approximately, between the lower ribs and the top of the legs), without or with leg pain (Koes et al., 2006). If the sensation of pain or discomfort is also experienced downwards into the leg, it is termed sciatica. According to Kendall et al. (1997), acute low back pain may be defined as activity intolerance due to lower back or back and leg symptoms lasting less than three months, although this definition fails to emphasise the sufferer's subjective experience of pain.

The possible causes of low back pain are multiple, including referred pain from elsewhere in the body, metabolic disorders, tumours, infection, inflammation and mechanical, otherwise known as structural, problems. The category of structural problems contains a number of conditions that may be readily diagnosed, for example, prolapsed intervertebral discs (herniated discs), spinal stenosis and stress fractures, as well as structural problems that it may not be possible to identify specifically. Unspecified structural problems can arise from everyday postural and mechanical stresses on the spine and its related ligaments and muscles. Maintaining static postures, such as

sitting or standing for long periods, awkward lifting, twisting movements, flexion, extension and prolonged and repetitive physical work are all potentially pain inducing (Speed, 2004).

Most clinicians and researchers accept there are likely to be physical, causal explanations for the onset of low back pain even if a precise cause can not be medically diagnosed (Speed, 2004). The use of X-rays and modern imaging techniques such as Magnetic Resonance Imaging (MRI) has proven disappointing in correlating imaged tissue damage and the symptoms reported by low back pain sufferers; some with radiological evidence of abnormalities are pain free whereas others without apparent damage may have painful, even disabling, symptoms (Jensen et al., 1994; Kleinstuck et al., 2006). Radiographic evidence of low back abnormalities among individuals who are pain free at the time of imaging has also been shown to be a poor predictor of new onset low back pain (Foster, 1998). Van den Bosch et al. (2004) cite a probability figure of less than 1% for a radiographic image to identify the specific cause in any given case of low back pain.

Superior diagnostic imaging of the lumbar region may be offered by computed tomography (CT), based on emerging evidence from its use elsewhere on the body. Cervical CT can offer improved diagnosis for spinal injuries according to one US study at a single hospital (Kling, 2007), although in this study the effect of diagnosis on outcomes was not followed up and, importantly, safety concerns surround the significantly higher doses of radiation associated with using CT for spinal imaging.

It may be speculated that the use of imaging for people with non-specific low back pain might have unintended, negative effects. If images of abnormalities or even normal variations in the spine are taken to be objective evidence of “damage”, pathology can become the focus of the problem at the expense of biopsychosocial understanding and management of back pain (Biderman et al., 2003). Embarking on inappropriate medical investigations and interventions may contribute to the maintenance of musculoskeletal symptoms (Modic et al., 2005; Hadler, 1999).

3.3. Defining non-specific low back pain

Approximately 90% of low back pain relates to unspecified, usually presumed structural, causes (Koes et al., 2006). The vast majority of people experiencing low back pain therefore have “non-specific” back pain, which is also known by the interchangeable terms, “mechanical”, “simple” and “common” back pain. A diagnosis of non-specific low back pain could be viewed as an essentially negative diagnosis because it is founded on the absence of criteria for identifiable pathology. Alternatively, a “non-specific” diagnosis could be considered a management label as opposed to a disease label, that is, as a functional diagnosis (Mayou & Farmer, 2002). Indicators for serious spine pathology - which is rare, in the order of 1% of back pain consultations - can be successfully identified in primary care settings using “red flags” (Greenhalgh et al., 2006). Examples of red flags are early (<20 years) age at first onset of back pain and a prior history of a malignant tumour. People who are diagnosed with non-specific low back pain are usually treated as a homogeneous group, both clinically and by researchers, however, it is likely that this group with a common diagnosis encompasses a range of underlying, structural conditions and possibly some with quite different aetiologies, risk factors and prognoses. Assumptions of homogeneity in non-specific low back pain are therefore unwarranted.

3.4. Definitions of acute, sub acute and chronic low back pain

Most frequently, low back pain is categorised on temporal dimensions. The widely used definition of acute low back pain is pain that resolves within 12 weeks of onset. Acute low back pain is then contrasted with chronic low back pain, which is pain that has endured for longer than 12 weeks (Koes & van Tulder, 2006). Some researchers subdivide the initial 12 week period into acute low back pain that resolves within a six (sometimes four) week period and sub acute low back pain for pain that lasts between six (or four) and 12 weeks. However, the national charity, BackCare, uses the term sub acute as interchangeable with a term “acute-on-chronic”, defined in its glossary information sheet as: “repeated episodes of back or neck pain continuing for longer than three months” (www.backcare.org.uk).

Temporal categorisation (acute < 12 weeks and chronic > 12 weeks) fails to capture features beyond duration that typically differentiate acute and chronic low back pain, nor does it explicitly acknowledge people's common experiences of persistent but intermittent, fluctuating pain, which become, by default, recurrent "acute" low back pain (alternatively defined as acute-on-chronic by BackCare).

Whatever the cause and duration of low back pain, psychosocial, behavioural and biological factors mediate all individuals' pain appraisals and responses throughout that experience, however, it is the relatively important role of the psychosocial and behavioural variables that are characteristic of chronic low back pain with disability. A variety of psychological variables, such as pain related fear and anxiety and depressive mood, which may also be accompanied by physiological changes (Hagen et al., 2006), are implicated in persistent pain that is partnered by distress and functional impairment (Keefe et al., 2004).

In the view of Horn & Munafo (1997), it has become unhelpful for researchers and clinicians to view acute and chronic pain as fundamentally different from one another and separable on the basis of how long the pain lasts. Rather, for the development and maintenance of chronic pain, enduring pain can create an opportunity for some individuals' mediated pain responses to become entrenched and maladaptive, with disability following on as a consequence. In the words of van Tulder et al. (2002):

"Low back pain is not simply either acute or chronic but fluctuates over time with frequent recurrences or exacerbations." (p. 761)

That the boundaries between "acute" and "chronic" are to some degree blurred in low back pain remains largely disregarded. Researchers have traditionally emphasised investigating disabling, chronic low back pain and clinicians maintain different approaches to managing acute and chronic non-specific pain – in both cases, guided by temporal categorisation.

3.5. Early low back pain

In this thesis, early low back pain is defined as an episode of pain that has lasted between two and nine weeks, which may or may not be a first episode and is not associated with persistent disability. The period of two to nine weeks' duration was selected because many discrete episodes of non-specific low back pain are brief, often resolving spontaneously within two weeks of onset (van Tulder & Koes, 2006). Including people with low back pain that had lasted less than a fortnight in an early intervention study would increase the “noise” of the data given a large proportion of such participants would in any case be predicted to recover without additional treatment. The upper limit of nine weeks was chosen for clarity. The intervention being investigated for this thesis is a self help, audio CD programme that takes three weeks to complete; recruiting back pain sufferers whose pain had not lasted beyond nine weeks would allow participants to complete the intervention programme before reaching the 12 week time point for “chronic” low back pain as it is typically, temporally defined in the back pain literature.

3.6. The costs of low back pain

Low back pain is a costly condition in terms of personal suffering as well as being an economic drain on society. According to the most recent, U.K. estimate, direct health care costs for all low back pain in 1998 were £1,632 million, with about a third of that sum being met privately. Indirect costs, covering, for example, estimated production losses from work absenteeism due to low back pain, were calculated to amount to a further estimated £10,668 million (Maniadakis & Gray, 2000). The annual cost to the NHS of low back pain is reckoned to be over £500 million (U.K. Department of Health, 1994).

In the U.S.A., estimated figures for total, low back pain costs are in excess of \$100 billion per annum, two thirds of which relates to indirect costs that are largely associated with employment status (Katz, 2006).

The emphasis on indirect costs linked to paid work is one of the methodological difficulties with full economic evaluations of low back pain, in which the costs for sub sets of the studied population, such as some parents, elderly people and students, are likely to be harder to quantify. According to van Tulder & Koes (2006), the methodological quality of the few, published evaluations of the economic burden of low back pain has been generally poor. Notwithstanding, it is clear that a small proportion of those with low back pain account for a disproportionate amount of the total, associated expenses. Katz (2006) calculates that fewer than 5% of people with low back pain are responsible for 75% of all back pain related costs in the U.S.A. In developed countries, it is the minority of low back pain sufferers who decline into chronic pain and disability - variously estimated to be 5% of the total (Koes et al., 2006), about 6% (Croft et al., 1998) and between 5% - 10% (van Tulder & Koes, 2006) – who account for the largest part of national, economic burdens.

3.7. Epidemiology of adult, non-specific low back pain in developed countries

Low back pain epidemiology is concerned with how many people have the condition, the condition's patterns of distribution in the population and risk factors that are associated with its onset and subsequent development.

3.7.1. Prevalence, incidence and distribution

Low back pain is most common in middle age (35 years to 65 years) and most adults will experience some low back pain in the course of their lifetime. Estimates of prevalence, a measure of the proportion of a population with low back pain during a specified period, vary between non-developed and developed countries, between developed countries, within developed countries according to different studies and across different regions within single countries (Manek & MacGregor, 2005). The variance may partly reflect methodological difficulties inherent in epidemiological research into a subjectively experienced, self reported condition that has a pattern of recurrence and remission (Macfarlane et al., 2006). According to the International Association of Pain, life time prevalence for low back pain is between 58% and 84% (Dionne, 1999), whereas slightly lower life time prevalence estimates for developed countries – between 49% and 70% - are

cited elsewhere, for example, by Koes et al. (2006). British lifetime occurrence is estimated to be 70% by age 60 in the 1998 Office of National Statistics Omnibus Survey in Great Britain.

The experience of rising absenteeism in the latter half of the 20th century and rising bills for incapacity benefits due to back pain is shared by the U.K. and other developed countries (Moore et al., 2003). It has been speculated these rises could be accounted for, at least in part, by changing attitudes and expectations (Palmer et al., 2000; Croft, 2000). There is little epidemiological evidence for changes in back pain pathology in the same period (Moore et al., 2003). It might be thought that changing work patterns during those decades, particularly the rise of sedentary employment, may have contributed to more low back pain, however, evidence to support this explanation is not strong (Barnekow-Bergkvist et al., 1998; Papageorgiou & Macfarlane, 1997) while other societal changes, such as less heavy, manual labour, would be more likely to be associated with lower back pain reporting. Croft (2000) concludes:

“Any explanation must strike a balance between the reality of the pain for the sufferer; the likelihood that mechanical factors can aggravate symptoms; the strong evidence that distress and dissatisfaction in daily life make back pain more likely and more persistent; and the possibility that public attention was increasingly drawn to the back during the 1990s.” (p. 1553)

Palmer et al. (2000) published findings from two postal surveys of one year prevalence in the U.K., carried out 10 years apart. Response bias might have affected these prevalence findings because, although the postal surveys were large scale, both had return rates of less than 60%. Palmer and colleagues found that one year prevalence had increased during the 10 year period by 13%, from 36% in the late 1980s to 49% in the late 1990s. The rise was consistent across ages and for both sexes. The authors note that severe back pain, defined in these surveys as low back pain making it impossible to put on one's own hosiery, fell during the same decade. They hypothesise that shifts in cultural attitudes may have made it more acceptable to take time off for less disabling low back pain than had been so 10 years earlier. The unknown origins of the vast majority of low back pain problems make it difficult to state with confidence what might underlie the reported rise in mild to

moderate low back pain coupled with an apparent fall in severe low back pain as measured by the hosiery test.

Increased U.K. prevalence, possibly linked to an increased, public awareness of musculoskeletal symptoms, was confirmed by a recently reported study that compared historical data collected by the Arthritis Research Campaign in the 1950s and data from a cross sectional, population survey carried out 40 years later. Harkness et al. (2005) investigated the reported presence of low back pain symptoms, shoulder pain symptoms or widespread pain symptoms on the day of the surveys. They found that for all of the symptom sites, the rise in prevalence in 40 years was between two and four-fold. In the second survey, women reported more pain for all three sites than did men.

Research into low back pain incidence, or onset, in the U.K. found more than a third of people without low back pain at the beginning of a study by Croft et al. (1999) reported developing at least one new episode of low back pain during the year following recruitment. Croft et al. surveyed 2,175 pain free adults for baseline data on potential predictors of low back pain. A second postal questionnaire 12 months later showed that 34% of the women and 37% of the men had experienced new low back pain in the interval between surveys. A lower U.K. incidence was more recently reported in a community study by Waxman et al. (2000), who found that 18% of adults, previously always back pain free, reported having a new episode of low back pain during the study. The Waxman et al. (2000) study used two postal questionnaires, three years apart, to survey 1,455 adults, some with and some without back pain at baseline.

Again, incidence studies are hampered by methodological difficulties. Findings will be affected by how long study recruits had been free of back pain before joining the study – past experience of low back pain is itself a strong predictor of future low back pain (Pederson, 1981) – by recall bias and by what is deemed to constitute an “episode” of low back pain. Community studies are valuable because it is known that the incidence of low back pain among the general public is not equivalent to the incidence of seeking NHS care for low back pain. It has been reported as few as 20% of adults in the U.K. with a new episode of low back pain consult their GP (Papageorgiou &

Rigby, 1991), although exactly who chooses to consult with an episode of back pain and what makes some do so and others not is less clear. It may be speculated that the psychological variables identified earlier as playing a role in the onset and development of non-specific back pain, such as depression, distress and maladaptive back pain cognitions, as well as pain intensity, may also be implicated in medical help seeking.

In addition to studies of prevalence and incidence, epidemiologists have investigated how low back pain is distributed in the population. Individual risk factors associated with low back pain are reported, including age, socio-economic and educational status, being a smoker, sex and occupation. With the exception of age, particular occupational factors (see below) and an increased prevalence in lower socio-economic groups, much of the available epidemiological evidence is inconsistent. Smoking has been repeatedly reported as a risk factor for low back pain, however, a systematic review (Leboeuf-Yde et al., 1996) concluded that the association was weak and smoking should be viewed as a complex indicator of risk, not a causal factor. Some reviewers conclude there is little evidence to support sex differences in low back pain (for example, Moore, et al., 2003) while others note an excess prevalence in women (for example, Macfarlane et al., 2006).

Many investigators have focussed on researching occupational risk factors for low back pain incidence. Occupational risk factors may be of a biomechanical nature. Some sportswomen and men are likely to be at increased risk of low back pain because of exposure to overuse and traumatic injuries (for example, Villavicencio et al., 2006). In other workplace settings, researchers have demonstrated a significantly increased risk of developing low back pain among those employees whose jobs entail heavy lifting and frequent, manual handling activities (Burdorf & Sorock, 1997), although findings from investigations into these risk factors in the general population have been more equivocal (for example, Thorbjornsson et al., 1998). Evidence to support associations between the development of low back pain and postures adopted for performing workplace tasks has also been reported (Macfarlane et al., 2006). Such postural risk factors include prolonged standing, working while bent forwards or kneeling and exposure to whole body vibration.

The intensity of the pain experienced during the acute phase of low back pain may be a risk factor for poorer outcome. Hazard et al. (1996) found a weak, positive relationship between pain intensity and absence from work at three months, although an earlier study (Hellsing & Linton, 1994) found no such relationship for sick leave measured at 12 months. More up-to-date research now suggests that the relationship between high levels of pain in the acute phase and both simultaneous and future disability may be stronger than was previously reported (for example, Gheldof et al., 2006; Sieben et al., 2005a).

Genetic studies, such as a twin study in the U.K. by Sambrook et al. (1999), indicate an important role for genetic factors in individuals' susceptibility to degenerative processes of the spine. However, the role of genetic factors in the experience of low back pain symptoms remains unresolved.

It has also been suggested, despite little available evidence to date, that people reporting physical or sexual abuse may potentially be at significantly increased risk for a variety of painful conditions, including low back pain (Linton, 2000). A "pain prone personality" has also been mooted but a search for supporting evidence for this notion has floundered (Gatchel & Weisberg, 2000). Studies investigating whether personality traits, usually as measured by the Minnesota Multiphasic Personality Inventory, are risk factors for long term pain and disability have produced mixed and inconclusive findings (Wade & Price, 2000). There is some evidence that the personality trait of neuroticism, or a general construct of negative affectivity, is related to a reduced threshold for perceiving a painful sensation to be threatening (Gheldof et al., 2006). In the view of some of the most prominent, current, pain researchers, negative affectivity may be construed as heading a hierarchy of interrelated traits that bestow vulnerability for maladaptive pain appraisals. Referring to negative affectivity, anxiety sensitivity (Asmundson et al., 1999) and fear of pain, Leeuw et al. state:

"Although it is not quite clear which specific trait is important for the development and course of low back pain, it may be suggested that certain, relatively stable vulnerability traits are important." (2007, p. 82)

Psychopathology, rather than personality traits, seems to have a clearer role; significant associations are reported between disabling, chronic low back pain and personality disorders, particularly depression and anxiety related personality disorders (Gatchel et al., 1995; Weisberg & Keefe, 1997; Sadigh, 1998).

3.7.2. Psychosocial risk factors

Epidemiological studies reveal an array of psychosocial factors that are implicated in reports of low back pain and work absenteeism, particularly in the U.K., high levels of job dissatisfaction (Papageorgiou & Macfarlane, 1997), poor social support at work and a low degree of job control (Macfarlane et al., 2006). The role of psychosocial variables has been widely researched in health care settings and among the general public as well as in the workplace. Most of this literature focuses on people who have chronic disability because of the associated distress and economic costs. Investigators of psychosocial factors have also tried to resolve questions surrounding the influence of psychological variables on the transition process from experiencing acute low back pain to developing chronic pain and disability.

The transition to disabling, chronic low back pain is influenced by individual variables, including occupational factors, and social variables as well as psychological factors and, as yet, the process is not entirely understood. Recent reviews strongly implicate some psychological factors, however, notably maladaptive cognitive processing, pain behaviours, somatisation and depressive mood (Koes et al., 2006; Pincus et al., 2002).

A large, German cohort study of elderly men and women found that depression increased the odds of disabling back pain two years later, independent of functional and medical status and socio-demographic variables. Further, having disabling back pain similarly increased the odds of developing depressive symptoms two years later (Mayer et al., 2007). In addition to a role in the transition to disabling, chronic pain, depressive mood may be implicated in new onset low back

pain (Croft et al., 1995). A longitudinal study in the U.S.A. found depression to be an antecedent and independent risk factor for first onset low back pain (Larson et al., 2004). In this study with a follow up period of 13 years, the authors reported a time lag, typically about a year, between onset of depressive disorder and onset of first low back pain. Similarly, maladaptive cognitions, such as pain catastrophising and somatisation, may influence pain onset as well as the developmental course of low back pain.

Catastrophising refers to “thinking the worst” and dwelling on extreme and negative interpretations of the meanings of pain sensations. The literature provides a consistent body of evidence to support a relationship between catastrophising cognitions, disability and pain intensity in a range of pain patients (for example, Sullivan et al., 2002) as well as in community samples (Severeijns et al., 2004). With regard to back pain onset, Linton (2005) has reported that catastrophising cognitions about pain are linked to an elevated risk of low back pain incidence among employees who had been free of low back pain for the previous year.

Somatisation refers to heightened awareness of and attention to bodily sensations, in this context, particularly vigilance for pain sensations. For a review of the attentional processes involved in pain vigilance, see Crombez et al. (2005).

Perhaps the most comprehensively researched psychological factor has been pain related fear and anxiety. Theoretically, fear relates to an identifiable threat in the present, associated with the 'fight or flight' response, and anxiety is a reaction to a more diffuse sense of threat in the future. Anxiety is associated with preventative strategies such as vigilance and avoidance (Leeuw et al., 2007). In the pain literature, fear and anxiety are often used in tandem or used interchangeably (cf. Asmundson et al., 2004). Closely associated is the construct of fear avoidance, a term to describe behaviours intended to prevent anticipated, increased pain or physical harm by avoiding carrying out certain movements and activities. Such avoiding behaviours negate the possibility of disconfirming the fearful beliefs that particular actions will have painful or dangerous consequences and are implicated in functional disability and physical deconditioning (Leeuw et al., 2007).

Vlaeyen & Linton (2000) developed the Fear-Avoidance Model of musculoskeletal pain primarily to give a cognitive behavioural account of the transition process from acute to chronic pain, however, much of the subsequent, vast body of research using the model has investigated how chronic pain and disability are maintained. A smaller number of studies using the model relate to low back pain in the acute phase. Here, relationships between pain related fear and reduced daily activities, increased perceived disability and higher sickness absence have all been reported (Leeuw et al., 2007).

Prospective studies also demonstrate some support for the role of pain related fear in the acute to chronic transition. Initially high levels of pain related fear in the acute phase of low back pain have been reported to contribute to a higher, future likelihood of chronic pain and to greater disability and work absenteeism (Leeuw et al., 2007; cf. Sieben et al., 2005b). However, closer examination of the evidence suggests that baseline measures of pain related fear may be less significant than the course of fear related variables in the very early weeks of low back pain. Those with an initially low measure of fear avoidance that goes up during the acute phase may be equally at risk as those who maintain an initial, higher level of fear avoidance. They are at even greater risk than those with high, baseline levels of pain related fear who show a reduction during the first two weeks (Sieben et al., 2002).

These detailed findings suggest it is the early, developmental course of fear avoidance, not its baseline measure, that may confer vulnerability. A very early approach to managing low back pain, designed both to prevent initially low pain related fear from growing and to reduce it where it is initially high, may be a more fruitful strategy than trying to identify and intervene with a “high risk” sub group based on elevated baseline measures.

Taking multiple measurements of unfavourable prognostic indicators at different time points would take account of the phenomenon of regression to the mean (Barnett et al., 2005). One U.K., primary care study has shown that repeated assessments can significantly improve the prediction of prognosis for low back pain patients (Dunn & Croft, 2006). The study found that the presence of

risk indicators, including catastrophising and fear avoidance, both at baseline and one month later was associated with significantly poorer outcomes than their presence at only one or no time points. Interestingly, the authors note that only about 50% of patients with high risk indicators at the initial assessment also had them at the second assessment.

The instability of some prognostic indicators following a GP consultation for low back pain does not appear to continue indefinitely, according to Dunn & Croft (2006). They suggest these early fluctuations settle with the passage of time and become relatively stable. There is tentative evidence that this stabilisation occurs within the first month of consulting (Dunn & Croft, 2006; Enthoven et al., 2003). However, 70% of the 359 patients who were followed up for 12 months in the Dunn & Croft (2006) study reported having had painful symptoms for six or more months at recruitment, which makes it difficult to draw a conclusion about the overall time scale of risk factor fluctuations, particularly for acute low back pain patients. In addition, it is not clear whether the increases and reductions in individuals' prognostic indicators between baseline and one month reflect random variation with regression to the mean or fluctuations in these measures for other reasons. The exception to the observed fluctuations in the month after consulting was among those study recruits who had no unfavourable prognostic indicators at baseline – only 6% of the total – most of whom maintained no adverse prognostic indicators a month later.

Dunn & Croft (2006) conclude that assessment at two time points improves the prediction of who has a poor prognosis and who therefore should be reassessed by the GP a year later, indicating their findings offer support for a “watch and wait” approach to non-specific low back pain patients. An alternative interpretation based on their findings might be that an early treatment intervention for the vast majority of GP consultees could address modifiable risk factors before those fluctuating factors become stable, and possibly maladaptive, a month later.

Fear related variables may have dominated recent research into psychological risk factors and have produced some interesting findings but it is important to note that not all the findings have been consistent or strong. A systematic review of low back pain prognosis and pain related fear

concludes there has been undue emphasis on these variables at the expense of possibly more relevant, psychological factors (Pincus et al., 2006). Pincus et al. (2006) reviewed nine, acute back pain studies published between 2001 and 2006 and reported that, overall, there was weak evidence for a relationship between high fear levels and poor prognosis in non-chronic low back pain. According to these reviewers:

“There is a growing consensus that distress/depression plays an important role at early stages, and clinicians should focus on these factors.” (2006, p. 3999)

Depression and distress, like fear avoidance, are potentially amenable to cognitive behavioural, early treatment.

Research into psychological factors and pain presents problems. Methodological difficulties may arise from reciprocal interactions between the psychological variables under study and subjective pain intensity, from overlaps in constructs and measures and from the variable, developmental nature of pain over time:

“... because factors may have different effects at different time points, thus creating innumerable combinations of a given risk factor’s effect in relation to the developmental stage (e.g., acute, sub acute, recurrent or chronic).” (Linton, 2000, p. 1148)

In his systematic review of 37 prospective studies of psychological factors, Linton (2000) identified specific methodological weaknesses in some of the studies included in his review. He highlighted the possibility of inflated effect sizes due to intercorrelation of measures. Depression and pain catastrophising may be intercorrelated, for example (Cooke et al., 2006; Pincus et al., 2002). He also noted selection bias and failure to control for confounding factors. Further, when similar psychological constructs were given different terms and measures it was hard to summarise clearly the available evidence. Feeling disinclined to take part in activities because of pain was variously termed “fear avoidance”, “disability” and “somatic anxiety” by different authors included in the review.

Despite these methodological issues, the systematic review by Linton (2000) concluded that robust data from a range of study settings strongly support the role of psychosocial variables both in the onset and in the subsequent development of back and neck pain. Specifically, in the cognitive domain, it strongly supported a relationship between pain onset, pain development and pain related disability and passive coping attitudes, catastrophising cognitive styles and fear avoidance beliefs. In the emotional domain, it reported strong evidence to associate depression, anxiety and distress with the onset and development of both acute pain and chronic pain and disability. In the behavioural domain, pain behaviours and functioning were found to be significant factors in all pain. Weaker evidence was found in the social domain to implicate some family and occupational variables.

A subsequent systematic review (Pincus et al., 2002) also concluded that psychological variables were determinants of chronic pain in prospective cohorts of low back pain sufferers. These reviewers included six trials that met the review's acceptability criteria. The authors did not report strong evidence to support a relationship between fear avoidance beliefs or catastrophising and the onset and development of low back pain. Rather, depressive mood, distress and, to a lesser extent, somatisation were found to be the main factors in the transition from acute to chronic pain. The effect size for these psychological variables was moderate, more influential than physical, clinical signs measured in the same study samples. Coping styles were found to have a weak role (cf. Linton, 2000).

A 2006 study to examine the prognostic value of active and passive coping styles in primary care patients in the U.K. found that those who reported passive coping strategies in acute low back pain had a three-fold risk of persistent symptoms at three month follow up. The risk remained, somewhat attenuated, after controlling for baseline pain severity and disability and other measures of pain history (Jones et al., 2006). High, reported levels of active coping did not appear to confer benefit. In this study, coping styles were evaluated using the Vanderbilt Pain Management Inventory in which respondents rate how often, despite pain, items such as “staying busy or active” and “distracting your attention from the pain” (active coping) and “depending on others for help with

your daily tasks” and “thinking, I can't do anything to lessen this pain” (passive coping) were applicable to them. Jones et al. (2006) point out that coping styles, in common with other cognitive and behavioural factors, are potentially important because they offer the prospect of modification through CBT based interventions.

Accumulating research evidence to implicate psychological factors in acute low back pain, in the transition process from acute to chronic pain and in the maintenance of chronic pain with disability is certainly strong. Nonetheless, psychological factors can only account for a portion of the variance. A raft of psychosocial factors may be useful for identifying low back pain sufferers at higher risk of developing persistent pain and disability - and comprehensive, psychosocial screening instruments have been developed to assess those whose acute back pain fails to resolve (Kendall et al., 1997; Boersma & Linton, 2005) - but no single psychosocial factor has been shown to offer good predictive power (Hartvigsen et al., 2004).

While comprehensive, psychosocial screening assessments are of theoretical use, the time required to complete and score such instruments means they are likely to be impracticable for routine use in GP surgeries (Jellema et al., 2007). If strong risk factors could be identified, modifying those risk factors in primary care would offer a powerful tool for reducing the impact of low back pain; as with psychosocial factors, no single occupational or other individual risk factor is a strong adverse prognostic indicator. Instruments to help GPs to identify low back pain patients with poor prognoses were compared in a study in The Netherlands (Jellema & Hallden, 2007). The study compared risk estimation by GPs based on their own knowledge and clinical expertise, the Orebro Musculoskeletal Pain Screening Questionnaire (Linton et al., 1998), the Low Back Pain Perception Scale (Reis et al., 2000) and a clinical prediction rule that was derived from multivariate analysis for the study. The authors reported that GPs' own predictions of the likely course of patients' low back pain were as successful as using the screening tools and that GP judgement seemed the best available option at present:

“... not because this 'instrument' gives such excellent results but because it is simple, the

assessment can be completed quickly and its calibration and discrimination do not differ substantially from the other instruments.” (2007, p. 21)

A different approach to identifying high risk patients in primary care has been taken by Mallen et al. (2007). They endeavoured to identify generic, rather than site specific, prognostic indicators for patients with musculoskeletal pain. Their systematic review included 45 studies, of which 27 were studies of low back pain. Eleven baseline factors were reported to be associated with poorer prognosis: initial pain severity; pain duration; multiple sites of pain; a history of painful episodes; anxiety and/or depression; somatisation and/or distress; adverse coping styles, poor social support; older age; greater initial disability; and greater movement restriction.

Mallen et al. (2007) state that, even if the generic prognostic indicators identified in their review were used together with site specific risk factors to evaluate risk:

“... it may still be difficult to provide individual patients with an accurate prognosis.” (p. 660).

Notwithstanding, the dominant focus of current low back pain research remains on identifying individuals with sub acute, non-specific low back pain who are at greatest risk of poor outcomes, with a view to tailoring interventions to divert them from declining into chronic disability (Koes et al., 2006). According to Koes et al.:

“The main challenge is the early identification, for example, based on psychosocial risk factors, of patients at risk for chronicity and subsequently preventing the chronicity from occurring.” (2006, p. 1430)

The reasoning is this should lead to the efficient and effective allocation of resources to the small minority whose unfavourable, long term outcome will account for the highest distress, disability and back pain related economic costs. Current evidence supports multidisciplinary intervention packages for persistent pain patients with complex difficulties but providing such treatment is

labour intensive and expensive (Morley et al., 1999; Hay et al., 2005), hence the focus on selection of people who might benefit earlier from a prior, less intensive intervention. As the literature reviewed here demonstrates, achieving the aim of reliable selection of particular individuals at greatest risk of poor outcomes remains problematic, as does which treatment or treatments should then be offered to them (Turk & Flor, 2006). There is some, initial evidence to encourage the aim of offering matched treatments to non-specific back pain patients with sub acute pain (Brennan et al., 2006).

Even if a practicable screening tool with the desired sensitivity and specificity were available in primary care, identifying those who are immediately at higher risk of developing chronic pain and disability may fail to address the needs of the many acute low back pain patients who make a complete or partial recovery from a discrete episode but who then go on to have repeated bouts of acute low back pain. A sustained pattern of acute recurrence and remission may itself be a long term precursor of chronic disability, perhaps many years down the line (Critchley & Hurley, 2007).

3.8. Prognosis

The prognosis for a discrete episode of acute low back pain is generally considered to be good (Koes et al., 2006), supported by evidence from a meta analysis of 15 prospective studies recruiting patients with pain of less than three weeks' duration (Pengel et al., 2003). Pengel et al. (2003) found substantial improvements in pain and disability within one month and further improvements at follow up at three months. For those initially off work, a pooled estimate of 82% was reported for return to work within one month, which rose to over 90% by six months. Nonetheless, these reviewers noted that lower levels of pain and disability continued and that recurrent episodes were common. Recruitment at less than three weeks' duration is also likely to influence the prognostic findings towards more favourable outcomes given that those discrete episodes that do resolve spontaneously and quickly generally do so within the first few weeks (van Tulder & Koes, 2006).

A notion that the vast majority of acute low back pain episodes resolve spontaneously and quickly is seriously challenged by a Danish, five year, prospective study of the course of low back pain in the general population. Hestbaek et al. (2003) found between 42% and 75% of participants still experienced some pain after 12 months. Further, findings from the U.K. (Burton et al., 2004) suggest many low back pain patients continue to experience back pain symptoms, sometimes with disability, at four years, even if they are no longer presenting for medical care. Burton et al. (2004) investigated a cohort of 252 low back pain patients attending for spinal manipulation. At one year follow up, 78% of questionnaire respondents reported incomplete recovery; at four year follow up, 59% reported pain symptoms and 49% claimed residual disability.

The outcome measure for recovery affects how favourable or otherwise the prognosis seems. Returning to work (Pengel et al., 2003; Schiottz-Christensen et al., 1999) is not equivalent to becoming free from pain and disability. Similarly, stopping consulting (Burton et al., 2004; Croft et al., 1998) can not be interpreted as recovery from symptoms. Croft et al. (1998) investigated the outcome of low back pain in general practice in the U.K. and found that while 90% of patients had stopped consulting within three months, only 21% were without any pain and disability at three months, rising to 25% at 12 months. Approximately 40% of patients reported persistent and disabling low back pain symptoms three months after an initial, GP consultation in a study by Jones et al. (2006). Findings of ongoing, back related problems among primary care patients in the U.K. are further supported by evidence from Thomas et al. (1999), who found that some disabling pain at 12 months was reported by approximately a third of GP, "acute" low back pain patients.

Patients with persistent pain measured at sequential follow up points are likely to represent a mixture of those who experienced continuous pain and those who had one or more recurrences during the study period. Data from a study from The Netherlands demonstrated that of GP patients still reporting pain one year after the initial consultation, only 10% were suffering from the original episode. Three quarters of participants in this study reported at least one recurrence during the year long trial (van den Hoogen et al., 1998). A Scandinavian, general population study with a five

year follow up reported up to 66% of people experienced back pain recurrences (Mortimer et al., 2006).

In contrast to the studies described above, a French study into the clinical course of acute low back pain, which also followed up patients independently of their continued use of primary care, found that 90% of patients had completely recovered within two weeks of their first consulting the GP (Coste et al., 1994). A possible explanation for the discrepancy is the unusually early recruitment window for this study, which restricted enrolment to people consulting within three days of pain onset. It is recognised that many discrete episodes of acute low back pain resolve within a fortnight (van Tulder & Koes, 2006).

According to Croft et al. (1998), prognosis findings from interview and questionnaire studies are at odds with a widely maintained view that most acute low back pain seen in primary care will resolve within a month. They write:

“We should stop characterising low back pain in terms of a multiplicity of acute problems, most of which get better, and a small number of chronic, long term problems. Low back pain should be viewed as a chronic problem with an untidy pattern of grumbling symptoms and periods of relative freedom from pain and disability interspersed with acute episodes, exacerbations and recurrences.” (p.1359)

3.9. Guidelines

Since 1996, GP management of acute low back pain patients should comply with Clinical Guidelines (Hutchinson et al., 1996) published by the Royal College of General Practitioners (RCGP) and updated in 1999 and 2001. The guidelines recommend triage of patients into “red flags” – those with indicators for serious, spinal pathology - those diagnosed with possible nerve root problems and, the majority, those with non-specific low back pain. For the latter, GPs are recommended to offer reassurance and information, perhaps including “The Back Book”. This is an evidence based booklet written by a multidisciplinary team of researchers, which is designed to encourage self management by patients (Burton et al., 2002). Consistent with the booklet contents,

GPs are advised to encourage patients to keep active and to continue normal, daily activities, including working, if possible. Advice gradually to increase exercise levels is also recommended although specific back exercises are not.

Treatment consists of prescribing regular, oral analgesia to control the pain, with referral to an NHS physiotherapist for patients whose symptoms persist for six weeks or more. Spinal manipulation could be considered for patients who are deemed to need additional help with short term pain relief and who are failing to return to work or their other, normal activities.

Routine imaging for non-specific low back pain is not recommended, nor is referral to medical specialists (except in “red flag” cases).

The U.K. guidelines are evidence based and are largely consistent with guidelines for managing acute low back pain in primary care in many developed countries, including Australia, Denmark, Finland, Germany, Israel, The Netherlands, New Zealand, Sweden, Switzerland and the U.S.A. (van Tulder & Koes, 2006).

3.10. Summary of Chapter Three

Most low back pain is “non-specific”. Non-specific low back pain is a heterogeneous condition and one in which clear distinctions between “acute” and “chronic” are not always possible. Despite an apparently common assumption that the prognosis for an acute episode is good, the course of non-specific low back pain is often recurrent and persistent, a fact that may be overlooked in prognosis studies that use return to work or stopping consulting as outcomes. Multiple factors - biological, individual, behavioural and psychosocial - are implicated in the onset and subsequent development of all non-specific low back pain.

Rising reports of low back pain and consequent absenteeism and benefits payments have been growing problems for the U.K. and other developed countries. The problem has generated a vast research effort to investigate chronic low back pain with disability. There is a smaller body of

research relating to the non-chronic stage of non-specific low back pain. The dominant research focus now is on investigating risk factors, particularly psychosocial risk factors, that may help with the earlier identification of the minority who will develop persistently disabling, chronic low back pain and who account for the majority of back pain related costs. This research has advanced the understanding of psychosocial risk factors associated with the onset of acute episodes and with the transition from acute to chronic disability. In the psychological domain, there is evidence to support a role for maladaptive cognitions, such as catastrophising and somatisation, depression, distress, pain related fear and passive coping styles, all of which are potentially modifiable through cognitive behavioural based interventions. However, to date the research has failed to translate into better, early treatments for acute episodes of non-specific low back pain nor improved long term outcomes for back pain sufferers.

U.K. guidelines for management of acute, non-specific low back pain essentially recommend an initial “watch and wait” approach, paired with advice to stay active and to take analgesics.

- No single, psychosocial (or other) factor is a strong determinant of outcome in acute, non-specific low back pain
- Comprehensive psychosocial screening instruments to detect groups of sub groups of patients at higher risk for disabling chronicity have a limited role in primary care
- Current research is strongly focussed on measuring psychosocial risk factors to try to identify, and consequently to successfully treat, groups of sub acute, back pain sufferers at higher risk of disabling chronicity, however, many problems remain to be overcome before either aim can be achieved
- There is a gap in the research: alternative, earlier treatment strategies, also based on the limited, available evidence, are not being pursued

- One such alternative strategy might be a universal intervention in the initial stages to address several, known, psychological and behavioural variables that fluctuate in the initial phase with potential implications for future outcomes

4. Chapter Four. Psychosocial interventions.

4.1. Introduction

This chapter continues the review of evidence on non-specific back pain by considering the research that relates to psychosocial interventions for low back pain, before it has become “chronic” or persistently disabling. Psychosocial interventions are taken to include studies that aim to provide psychosocial education at the population, community or individual level; studies investigating physiotherapy and other forms of delivery of interventions with a cognitive behavioural orientation; and the few studies that have specifically used CBT, including CBT programmes designed explicitly to enhance self care. The stepped care model for managing low back pain in primary care is described more fully. The chapter reviews evidence from developed countries.

4.2. Psychosocial education

Public health campaigns designed to address maladaptive, low back pain beliefs in a population may be an effective means of reducing back pain related disability, although there is inconsistent evidence emerging from different countries (Buchbinder & Jolly, 2005; Waddell et al., 2007). A two year, Australian, health education campaign in the state of Victoria was evaluated by comparing telephone surveys of beliefs about low back pain, including fear avoidance beliefs, before, during and after a local, media campaign, both in a population sample in Victoria and in a matched population sample from a neighbouring, control state (Buchbinder & Jolley, 2005). A total of 6,230 people completed the surveys. At the end of the state wide media campaign, statistically significant changes in back pain beliefs were recorded among residents and doctors in Victoria. These were accompanied by a decrease in the number of workers' compensation claims for back related problems. No comparable changes were found in the neighbouring, control state. The improvements in public and professional beliefs about low back pain in Victoria were sustained three years after the health education campaign had ended. Subsequently, GP beliefs, combined with corresponding, self reported changes in their management of back pain, were found to persist four and a half years after the campaign (Buchbinder & Jolley, 2007). The findings by Buchbinder &

Jolley indicate widespread, low level education can be a successful strategy for reducing low back pain disability and related payments.

In Scotland, the results of a national, multimedia campaign, "Working Backs Scotland", have also been reported (Waddell et al., 2007). This was a population level intervention to target beliefs about low back pain management, both among the general public and among Scottish health professionals. The campaign consisted of information packs about back pain for employers, for back pain sufferers and for all health professionals involved in treating back pain, in combination with some 2,000 radio advertisements and a specially created website: www.workingbacksscotland.scot.nhs.U.K. The focus of the educational material was on managing back pain through staying active rather than resting, in accordance with current U.K. guidelines. It is estimated that the national campaign has reached 60% of the country's population (Waddell et al., 2007).

Sickness absence and new, back related incapacity benefits were compared between Royal Mail employees in Scotland and Royal Mail employees elsewhere in the U.K., before and three years after the start of the campaign. In addition, population samples were surveyed monthly before the start of the campaign and at monthly intervals thereafter for beliefs about staying active versus resting, help seeking behaviour for back pain and professional advice on its management. Waddell et al. (2007) found that within one month of the campaign starting there was a significant change in back pain management beliefs. Initially, some 55% had believed in rest for back pain, which was reduced to about 30%. About 40% had initially believed in the benefits of staying active and this was increased to 60%.

While the public campaign's impact on back pain related beliefs represented significant improvements, it is noteworthy that substantial minorities of the Scottish population nonetheless appear to retain positive views of bed rest as a treatment for back pain (30%) and to remain not persuaded of the benefits of physical activity in back pain management (40%).

Waddell and colleagues reported that the observed, early improvement in back pain management beliefs was maintained at three years and it was reportedly allied to comparable changes in professional advice for managing back pain. However, despite a sustained change in public beliefs and professional advice about back pain management, no effect was found for work related outcomes. No changes were observed for rates of absenteeism or of new, back related incapacity payments. This contrasts with the Australian study (Buchbinder & Jolley, 2007) in which a public health campaign's impact on back pain beliefs was also accompanied by evidence of economic benefit. To date, there are inconsistencies in the available evidence on the impact of public health campaigns. Changing back pain related beliefs may not in itself be sufficient to improve back pain outcomes.

A potentially positive impact of disseminating up-to-date information and advice for managing low back pain had been demonstrated earlier in the U.K. with an evaluation of primary care patients' beliefs and clinical outcomes following the introduction of "The Back Book" (Burton et al., 1999). "The Back Book" is an evidence based, educational booklet advocating active coping, maintaining activities and either staying at work or an early return to work after an episode of acute low back pain. A double blind, randomised controlled trial investigated back pain beliefs, including fear avoidance beliefs, self reported functional disability and self reported pain intensity among 162 individuals who had received either "The Back Book" or a traditional, biomedical information booklet about back pain. The results demonstrated that those who had received the modern booklet showed greater, early improvement in their beliefs about actively managing back pain and that these statistically significant improvements were maintained at one year follow up. Early reductions of initially high fear avoidance beliefs among the experimental group were associated with subsequent, clinically significant decreases in self reported functional disability at three months. There is limited, positive evidence for "The Back Book" for U.K. primary care patients, based on a single randomised controlled trial.

A systematic review of the effectiveness of patient information materials for non-specific low back pain was published in 2006 and included 13 trials, 11 of which were randomised controlled trials

(Henrotin et al., 2006). The reviewers concluded that patient information booklets improved knowledge and back pain related beliefs. However, they reported no evidence of an effect on work absenteeism and inconsistent and inconclusive evidence of effects on various back pain specific outcomes and patients' use of healthcare resources.

Taken together, these findings indicate there can be a role for early education and advice that can help challenge unhelpful beliefs and behaviours with regard to non-specific low back pain. Improved clinical outcomes as a result may not always extend to reduced absenteeism and costs associated with sick leave and disability (Henrotin et al., 2006; Waddell et al., 2007). The overall cost effectiveness of implementing large scale, multimedia, health education campaigns therefore requires careful, financial evaluation. Similarly, even simple, individual level interventions have cost implications. "The Back Book" is available for purchase from the Stationery Office and it is at the discretion of GP practices whether or not to invest in supplies of copies for their patients. Consequently it is not known how many U.K. patients consulting with acute, non-specific low back pain have recommended, verbal advice on managing the condition supplemented by the written information in "The Back Book", despite research evidence from a single randomised, controlled trial to support its use with respect to beliefs and functional outcomes at three months.

Evidence for improved outcomes from preventive, education based interventions in the workplace is still less compelling. A systematic review of 10 controlled trials in various occupational settings found no evidence of effect on back pain related absenteeism or of economic savings for employers (Tveito et al., 2004). In addition, the reviewers reported weak evidence for no effect on future episodes of low back pain. However, the occupational interventions included in the review were mainly studies that involved education in back schools, which have variable programmes and may often give more emphasis to physical factors and to teaching lifting techniques than to psychosocial factors. An additional, educational study in the review involved the provision of an information booklet for employees; the booklet encouraged activity and had similar contents to the "The Back Book" available in the U.K. This study found no evidence of effect of the educational booklet on workers' absenteeism due to back pain (Symonds et al., 1995). This may appear to

contradict the findings of benefit from "The Back Book" by Burton et al. (1999) but the two studies were carried out with employees and primary care patients respectively and their outcome measures are not directly comparable.

A Norwegian, occupational study, published too recently to be included in the review by Tvieta et al. (2004), has reported significant differences between workers with sub acute low back pain assigned to usual primary care and those assigned to a spine clinic for education, reassurance and encouragement to keep active (Hagen et al., 2003). The intervention group returned to work more quickly and had significantly less sickness compensation in the following year. No significant, between group differences were observed during the second and third years of follow up.

Karjalainen et al. (2004) investigated a minimal intervention delivered outside the workplace, which focussed on education and physical activity, either with or without the addition of a workplace visit. A control group received usual care. They found that employees in the minimal intervention arm, with no workplace visit, had significantly fewer days off work and reported fewer symptoms than those receiving usual care, however, there were no significant differences observed between the usual care group and those allocated to a workplace visit in addition to the minimal intervention. It is not clear what underlies the apparently contradictory findings of this study. A further study by Anema et al. (2007) compared a multidisciplinary intervention in the workplace, with or without a graded activity component, versus usual care. In contrast to the study by Karjalainen et al. (2004), these authors reported that the workplace intervention alone significantly reduced the duration of absenteeism. However, no significant differences were observed for those in the study group that combined the workplace intervention with graded activity. The studies are not directly comparable with one another because of differences in the type and location of delivery of the minimal interventions for employees and, both separately and together, the findings are hard to interpret. One seems to suggest that a minimal intervention in the workplace alone is more effective than usual care whereas the other seems to suggest that only a minimal intervention outside the workplace, without any workplace visit, is more effective. Overall, the evidence for workplace interventions having positive benefits on absenteeism is weak and inconclusive, whereas the

evidence in favour of education and information and their influence on back pain related beliefs, although not absenteeism, is less weak.

4.3. Early intervention by the GP

In the only study of its kind, Jellema et al. (2005a) in The Netherlands developed a minimal intervention aimed at the identification and modification of psychosocial prognostic factors by GPs. Doctors in the intervention arm were given additional training to carry out an extended consultation (lasting about 20 minutes) with acute and sub acute, non-specific low back pain patients. During the extended consultation, the GP first explored the presence of psychosocial risk factors with the patient. Subsequently, in the consultation's information phase, the doctor provided reassurance and information about non-specific low back pain and its management, paying particular attention to addressing any identified, adverse psychosocial factors for that patient. A self care phase followed in which both parties discussed and agreed specific goals for individual patients to resume their normal activities. Patients also received "The Back Book". The trial was a well designed study with a relatively large sample size ($n = 314$). It found no statistically or clinically significant effects compared to usual GP care.

The authors of this study discuss the possibility that they found no evidence of effectiveness because the intervention by the GPs was too minimal, although they point out that a more intensive intervention, even if shown to be effective, would be unlikely to be adopted as normal GP care because of the time limitations for primary care consultations. Further, group differences may have been attenuated by the patients in the control group receiving some element of psychosocial care from the control arm GPs or from other therapists to whom they were referred. Another possible explanation concerns inadequate delivery of the trial intervention by the doctors, who had received five hours of training before the start of the study but whose implementation of the training was not monitored. Other authors have previously debated the merits of training health professionals who are not psychologists to deliver psychosocial and CBT based interventions (for example, Morgan, 2005). Macfarlane et al. (2006) question whether brief training programmes to

prepare healthcare practitioners to deliver psychosocial interventions are likely to be adequate; the intended psychosocial intervention may not be delivered, with implications for observed effects on outcomes (Macfarlane et al., 2006).

In a follow up study by Jellema and colleagues, the authors reported that GPs in the intervention arm demonstrated a less biomedical approach in back pain consultations than “usual care” doctors but they were nonetheless only moderately successful at identifying individual patients' psychosocial risk factors (Jellema et al., 2005b). This is consistent with the researchers' earlier finding that intervention arm GPs had failed to modify patients' adverse, psychosocial prognostic indicators during the extended, back pain consultations. The findings by Jellema and colleagues could be interpreted as lending support to those questioning the adequacy of health practitioners, who are not psychologists, implementing psychosocial interventions with brief training in psychosocial intervention delivery (for example, Macfarlane et al., 2006). The study by Jellema and colleagues is nonetheless important. It is the only, good quality trial to investigate enhancing Step 1 of back pain management and highlights some difficulties with implementing psychosocial interventions in primary care, particularly, training for intervention delivery and time constraints in GP consultations.

4.3.1. The role of health professionals' back pain beliefs

In the past, most researchers concentrated on patient characteristics to try to explain variable outcomes in non-specific low back pain. More recently, some researchers have begun to consider the role of the beliefs and behaviours of GPs and other health professionals involved in the care of non-specific back pain patients. An analysis of audiotapes of primary care consultations in the U.S.A. showed that patients' functional limitations due to back pain and specific strategies for them to resume normal activities were rarely discussed by patients and doctors, despite many of the patients reporting that they would have liked to talk about these matters (Turner et al., 1998). Guidelines recommend reassuring acute, non-specific low back pain patients about their condition, however, there is some evidence to indicate that the reassurance offered in a primary care

consultation may be inadequate to address some back pain patients' concerns and fears. Following a first primary care visit, more than half of back pain patients still feared wrong movements could lead to serious, spinal injury and almost half remained worried about future disability from back pain, according to Moore et al. (2000). These authors note that for acute, non-specific low back pain patients:

“Worries in this population are not minor concerns.” (p. 149)

Using medical jargon when giving investigation results and giving biomedical sounding, diagnostic labels to non-specific back pain may inadvertently increase patients' threat appraisals with respect to painful, back symptoms (Vlaeyen, 2006). Further, doctors' language – and more subtle, non verbal communication cues - may convey their own attitudes and beliefs about non-specific low back pain and these attitudes and beliefs may affect the advice then given to patients. Coudeyre et al. (2006) found a “considerable” number of GPs in France held high fear avoidance beliefs about non-specific back pain and that this could influence their adherence to clinical guidelines for its management. GPs with high fear avoidance beliefs were significantly more likely to prescribe sick leave and bed rest for acute, non-specific low back pain, contrary to best practice. An analysis of data from 709 GPs and 2,727 acute low back pain patients also reported significant associations between GPs' fear avoidance beliefs and those of their patients (Coudeyre et al, 2007). Coudeyre et al. (2007) stress the prognostic importance of fear related variables in the initial phases of non-specific low back pain, stating that:

“... key messages on this topic should probably be delivered at a very early stage.” (p. 720)

Similarly, Poiraudau et al. (2006) in France demonstrated that physicians' own fear avoidance beliefs and those of their sub acute back pain patients were significantly, positively correlated. Both this study and the studies by Coudeyre and colleagues were cross sectional and relied on self reported data, therefore the directions of the reported associations are not revealed and there may

be concerns about the possible impact of response bias among participants. It may be speculated, however, that responding doctors would be more likely to under report any failure to manage acute, non-specific low back pain in accordance with clinical guidelines. Referring to these recent French studies, Vlaeyen has commented:

“...the results are intriguing and call for a thorough reflection on their potential underlying mechanisms. For example, is it possible that the current concerns and fears of health care providers are actually 'contagious'?” (2006, p. 240)

The recent French studies accord with previous findings in other settings of health care providers' health beliefs, including the pain beliefs of physiotherapists, possibly influencing back pain management and, potentially, patients' outcomes (for example, Daykin & Richardson, 2004; Linton, 2002; Schers et al., 2001). Most recently in the U.K., Bishop et al. (2008) have suggested that addressing unhelpful beliefs and attitudes among health care professionals could lead to better outcomes for non-specific, low back pain patients. Bishop and colleagues analysed the data from 1,022 respondents to a postal survey of U.K. GPs and physiotherapists and reported finding diverse attitudes and variable, self reported, clinical management of non-specific, low back pain patients. The U.K. survey included the Pain Attitudes and Beliefs Scale and a vignette of a non-specific, low back pain patient, about whose hypothetical management the respondents were questioned. Most survey respondents indicated they would give advice that was broadly in accordance with current guidelines, according to Bishop et al. (2008), but 28% reported that they would advise the fictitious patient to stay off work, contrary to clinical guidelines. The authors report:

“Many health care practitioners held the belief that low back pain necessitates some avoidance of activities and work. The attitudes and beliefs of the health care practitioners were associated with their self reported clinical behaviour regarding advice about work.” (Bishop et al., 2008, p. 187)

The influence of U.K. health professionals' attitudes and beliefs regarding non-specific back pain and the possible impact of these on patients' attitudes and beliefs and, consequently, on outcomes

appears to warrant further investigation. Potentially, positively influencing the back pain related beliefs of health care professionals could offer the prospect of some improvement to current, Step 1 care for back pain patients. Caution is warranted, however, in view of the evidence from information giving studies reviewed earlier; overall, the evidence for changes in back pain related beliefs translating into better outcomes was inconsistent and inconclusive (Henrotin et al., 2006).

4.4. Physiotherapy

In the U.K., approximately 1.3 million low back pain patients a year are treated by NHS physiotherapists despite a weak evidence base for this practice (Hay et al, 2005; Frost et al., 2004). Referral to physiotherapy has been a major component of NHS GP care for sub acute, non-specific low back pain for years and perhaps remains so because GPs' treatment options for these patients are limited (MacAuley, 2004; Little et al., 1996). Given non-specific low back pain is a symptom rather than a disease, and may have a range of possible, underlying causes, it does not fit well within a biomedical model of diagnosis-treatment-cure (MacAuley, 2004). Patients referred for NHS physiotherapy are likely to be given an individualised programme that offers some combination of advice, spinal joint mobilisation and exercises to strengthen the lumbar spine and abdominal muscles. Spinal manipulation, available from private practitioners such as chiropractors and osteopaths and from some physiotherapists, is not a routine component of NHS physiotherapy (U.K. BEAM, 2004). The U.K. BEAM Trial Team investigated the cost effectiveness of spinal manipulation alone and of exercise classes preceded by spinal manipulation for primary care patients consulting with non-specific low back pain. Both interventions were compared with usual "best practice" in primary care. It concluded that spinal manipulation followed by exercise classes and particularly spinal manipulation alone could constitute cost effective additions to current U.K. practice (U.K. BEAM, 2004). The magnitude of the reported, between group differences was nonetheless small.

Findings by Frost et al. (2004) also challenge the current model of care in which family doctors routinely refer sub acute, low back pain patients for NHS physiotherapy. Their pragmatic, multi

centre, randomised controlled trial showed a course of NHS physiotherapy plus advice based on “The Back Book” was no more effective at 12 months than a single session of physiotherapist assessment and the same advice. The main outcome measure was the Oswestry disability index score at 12 months.

While the study by Frost et al. (2004) highlights the lack of persuasive evidence to support standard physiotherapy for non-specific low back pain, the research may be criticised. There was a large drop out of participants by the 12 month assessment (30%); some participants in the assessment and advice arm did receive additional physiotherapy sessions, contrary to the study protocol; and a large proportion of the “sub acute” participants, recruited with low back pain that had lasted for at least six weeks, might be temporally defined as chronic pain patients. Approximately a third of recruits had low back pain for more than 12 months, although it is not clear whether this represented continuous pain or repeated episodes. Despite heterogeneity in the participants and in the 76 therapists, it could be argued the trial did offer some support for a course of NHS physiotherapy in the shorter term, specifically in participants’ subjective ratings of treatment benefit at two and six months. This is in line with findings from some other trials, for example, Wand et al. (2004). It might also be argued that the Frost et al. (2004) results support existing, limited evidence (Burton et al., 1999) for the benefit of disseminating advice in “The Back Book” to encourage U.K. patients to actively self manage low back pain; both trial groups received the same educational advice based on the contents of “The Back Book”.

4.4.1. Psychosocial physiotherapy

Physiotherapy is also known as physical therapy, for example, in the United States and Australia. Unclear evidence on the long term benefits of physical therapy for sub acute and acute low back pain, concerns about potentially negative effects of perhaps fostering “the sick role” and caution about the additional expense of introducing early, active treatment may have contributed to some variation in international guidance on when any physical therapy should be started (Wand et al., 2004). Several guidelines for managing acute, non-specific low back pain, such as the U.K.,

Australian and Dutch guidelines, recommend that referral for physical therapies should not be considered until an episode of low back pain has persisted for at least six weeks whereas others, for instance, the American guidelines, suggest earlier intervention with physical therapies (van Tulder & Koes, 2006).

A pragmatic trial by Wand et al. (2004) was designed to clarify the impact of the timing of physiotherapy that took a biopsychosocial approach to acute back pain treatment. The U.K. trial compared the recommended model of care of assess, advise and wait with an experimental model of assess, advise and treat. Wand et al. (2004) concluded that, compared to the standard assess-advise-wait model, psychosocial outcomes for people with back pain of up to six weeks' duration significantly benefited from quicker introduction of active treatment. However, greater improvements in disability and pain observed in the early referral group, which were found at six week follow up, were not maintained longer term. Nonetheless, Wand et al. (2004) offer some intriguing, preliminary evidence to challenge the "watch and wait" model, particularly with respect to addressing psychosocial factors in the acute phase.

Efforts have been made to develop U.K. physiotherapists' treatments for low back pain and other musculoskeletal conditions by giving greater emphasis to working within a biopsychosocial framework (Watson, 1999), although to what extent psychosocial assessments and treatments are implemented by any particular therapist may be variable (Pinnington, 2001). A number of relevant research studies have now been published. In the U.K., for example, Hay et al. (2005) reported a pragmatic, randomised controlled trial to compare clinical outcomes in acute and sub acute low back pain patients assigned to different physiotherapy programmes. One programme was designed to encourage return to normal activities by addressing psychosocial barriers to recovery. This brief pain management package included education about pain mechanisms, encouragement of active coping, a graded approach to increasing activity and the development of personal plans for improving general fitness. It also included tailored, general exercises in the clinic and at home but did not include manual physiotherapy. Three physiotherapists received training to deliver the psychosocial pain management programme. The second package consisted of specific back

exercises, this time combined with education about the anatomy of the spine, ergonomic advice and a course of “best practice” manual physiotherapy. A different three physiotherapists delivered the alternative programme. The trial did not have a control arm without a physiotherapy intervention, which is a limitation of the design of the study.

The main outcome measure was back pain related disability at one year. Other measures assessed at three months and 12 months included subjective pain ratings, depression and somatic distress, fear of movement and coping strategies, plus absenteeism and use of health care resources. The researchers found no significant difference in clinical outcomes between the two intervention groups. While the physiotherapy packages were very similar with respect to functioning, reported pain and psychological outcomes, the pain management programme was delivered in fewer treatment sessions and resulted in significantly fewer referrals to secondary care than manual physiotherapy.

In the U.S.A., George et al. (2003) showed that using a four week physiotherapy programme that had been modified to address fear avoidance beliefs had equivocal outcomes compared to standard physical therapy. In a randomised trial of 66 consecutive patients with sub acute low back pain, both groups showed improvements in disability and pain. Those in the intervention arm showed significantly lower fear avoidance beliefs than controls, post intervention and at six months. However, further analysis of the results suggested that while patients with high fear avoidance beliefs benefited from the modified physiotherapy programme, those in the experimental arm with low fear avoidance beliefs appeared to fare worse than patients who received standard physical therapy.

An earlier, U.K. study investigated a course of physiotherapist led exercise classes that combined strengthening exercises, stretching, relaxation and psychosocial education (Klaber Moffett, 1999). The intervention was devised using cognitive behavioural principles although, unlike the George et al. (2003) study, no single psychological risk factor was targeted. The course consisted of twice weekly, hour long classes over four weeks. Recruits from GP practices had non-specific low back

pain of between one and six months' duration. Compared to controls receiving standard GP care, which may have included referral to routine NHS physiotherapy, the intervention group showed significantly greater improvements in measures of functioning and pain intensity at 12 months. Those in the intervention group also had significantly fewer days off work and used fewer health care resources during the year following the intervention. Consistent with a previous study recruiting only chronic back pain patients (Frost et al., 1995), the Klaber Moffett et al. study (1999) found that those in the intervention arm reported significantly less distressing pain than controls at six weeks, despite no comparable, accompanying changes in the reported intensity of their pain.

The paper by Klaber Moffett et al. (1999) highlighted the difficulties of recruiting study participants from primary care in the U.K. The authors also reported that the effects of the intervention on patient outcomes were unaffected by the patients' trial arm preferences prior to randomisation (cf. Goossens et al., 2005).

It is interesting to compare the findings of the 1999 Klaber Moffett et al. study, which used a psychosocial oriented programme of exercises and education, and the results of a subsequent study that focused on modifying pain related fear variables (Klaber Moffett et al., 2004). The second study had more equivocal findings. Again using a design that compared usual GP care with a psychologically oriented course of fitness classes, the authors hypothesised that patients with higher baseline measures of fear avoidance and of psychological distress would show greatest benefit from the intervention. A total of 187 adults with non-specific back pain of between six weeks' and six months' duration were recruited from primary care. Consistent with the findings by George et al. (2003), Klaber Moffett et al. (2004) reported that high fear avoiders significantly benefited from fitness classes that were designed particularly to address fear avoidance beliefs, however, low fear avoiders did not. The results of the Klaber Moffett et al. study (2004) also support previous research findings that suggested reductions in high fear avoidance beliefs precede improvements in functioning (for example, Burton et al., 1999), perhaps by positively modifying patients' self efficacy or sense of control over managing their pain (Klaber Moffett et al., 2004; Frost et al., 1995).

Compared to controls in the Klaber Moffett et al. study (2004), intervention patients with baseline, high psychological distress - related to somatisation and depression - showed significant improvements in distress measures at six weeks although this effect was short lived. The intervention programme consisted of eight, one hour sessions over a four week period. Average attendance was for only about half of the programme. The authors speculate that the short term, intervention benefit with respect to psychological distress may reflect an effect of exercising itself or may reflect benefit from social support derived from temporary membership of the exercise group, both of which likely ceased when the study intervention ended.

The positive finding that was maintained was restricted to high fear avoiders in the intervention arm and this benefit accrued despite many participants having failed to complete the full programme. Given the uncertainty about the value of a single "baseline" measure of an adverse prognostic indicator (Dunn & Croft, 2006) and the likelihood that initially fluctuating prognostic indicators settle over time (Dunn & Croft, 2006; Enthoven et al., 2003), it may be speculated that recruits with low back pain of up to six months' duration included people whose idiosyncratic psychosocial risk factors had already become stable. Hence, an interpretation of the 2004 (Klaber Moffett et al.) study would be that an exercise intervention designed to address high fear avoidance - and possibly a less intensive intervention than the one used in the study - is appropriate for a sub group of pain patients for whom high fear avoidance beliefs and behaviours have already become established, whereas the same intervention is less helpful for others. Plausible interpretations of the combined evidence from trials of psychosocial physiotherapy are that modifying patients' self efficacy beliefs with respect to managing their back pain and addressing psychosocial factors generally, before the sub acute phase, may offer benefit.

For the sub group of patients with established distress symptoms in the Klaber Moffett (2004) study, a longer or more intensive fitness intervention, or greater emphasis on goal setting and accessing exercise and social support after the trial, or possibly an alternative treatment for depressive symptoms, may have been a more appropriate treatment approach. To this author's

knowledge, there have been no randomised controlled trials of anti-depressant medication for patients with sub acute, non-specific low back pain.

Studies that have explicitly employed CBT, rather than a general, cognitive behavioural approach, will be considered in the following section, including one study that combined physiotherapy and CBT.

4.5. CBT interventions

The addition of CBT to physiotherapy was investigated by Linton et al. (2005). This Swedish trial aimed to ascertain the effect of group CBT alone or group CBT in addition to physical therapy on future absenteeism and health care use, with usual GP care of assessment, reassurance and advice as a control arm. The study enrolled 185 patients seeking care for acute, non-specific back or neck pain. At one year follow up, Linton et al. (2005) reported that the risk for developing long term disability was five times higher in the usual care, control group compared to both the CBT intervention group and the CBT plus physical therapy group. Results between the two interventions providing CBT were substantially similar, suggesting that CBT was the important component in preventing future disability.

Table 2: Overview of the six week, group CBT programme for spinal pain used by Linton and colleagues

Adapted from Linton & Ryberg, 2001.

Content of the six, weekly CBT sessions	Skills acquisition
Causes of pain and preventing chronicity	Problem solving, applied relaxation; pain education
Pain management	Activity scheduling; maintaining daily routines; relaxation training
Promoting good health and controlling stress	Warning signals; cognitive appraisals, beliefs
Adapting for work and leisure	Communication skills; assertiveness; risk situations; applying relaxation
Controlling flare ups	Planning for coping with flare ups; coping skills review; applied relaxation
Maintaining and improving results	Risk analysis; planning for adherence

The findings in support of group CBT for early back pain management accord with reported, significant benefits of group CBT for acute and sub acute spine patients in a three arm trial that investigated six sessions of coping oriented CBT versus six information sessions versus an information pamphlet, each in addition to usual primary care (Linton & Andersson, 2000). They are also consistent with a general population study by Linton & Ryberg (2001). It found people with multiple, intense episodes of spinal pain during the previous year who were allocated to group CBT fared significantly better than controls on measures of sick leave and disability. Group CBT was delivered by trained therapists in accordance with a manual.

A brief description of the contents of a group CBT programme devised by Linton and colleagues is given in Table 2.

One further CBT study was identified that investigated individual CBT for patients with acute sciatica. Hasenbring et al. (1999) reported that both individual CBT and a standardised electromyographic biofeedback intervention produced statistically and clinically significant improvements. CBT to address identified psychosocial risk factors was found superior in terms of pain reduction.

Any research involving a face to face, psychological or physical intervention raises questions about the possible impact of variations in therapists' characteristics and intervention delivery. The recommended method to control the independent variable in trials investigating psychological and physical treatments is to produce a manual that specifies the intervention and then to monitor therapists' adherence to that manual (Morley & Williams, 2002). This was done in the investigations into group CBT by Linton and colleagues, for example. It was not done in the Frost et al. (2004) study, where the large number of different therapists (76) particularly suggests the possibility of considerable treatment variation. The Hay et al. (2005) study involved six therapists, also not working to a manual. In this case, each therapist delivered only one of the two, possible treatments, which adds to the risk of individual therapist characteristics, such as competence or empathy, introducing bias.

While it would not be possible to remove therapists from manual treatments, the use of technology, such as CDs, to deliver psychological interventions would eliminate the problem of variation in health professionals' characteristics and treatment delivery in research studies. Arguably, this would be at the expense of exercising skilled, clinical judgement with individual patients (Morley & Williams, 2002). However, group CBT delivered in accordance with a manual is not an individualised, psychological treatment and yet still shows benefit (for example, Linton et al., 2005). Further, systematic reviews of evidence from self help trials have reported equivalent or nearly equivalent effect sizes of self help therapies and therapies delivered face to face (Marrs, 1995; Gould & Clum, 1993).

Taken together, the research reviewed here suggests that interventions by physiotherapists that specifically target fear avoidance, rather than address adverse psychosocial risk factors generally, may be ineffective, possibly even counter-productive, except perhaps where such treatment is restricted to a sub group of non-specific back pain patients who have already developed stable, fear avoidance beliefs and behaviours. The limited, available research does not clarify the possibility or utility of customising psychosocial physiotherapy for putative, high risk sub groups in the earliest stages of non-specific low back pain. As discussed earlier in the thesis, a single, baseline measure of a psychosocial factor in the initial phase is largely uninformative when such prognostic factors may fluctuate for some weeks after pain onset. Several of the studies reviewed in this chapter recruited a mixture of acute, sub acute and temporally chronic pain patients. The developmental nature of pain over time, the heterogeneity of non-specific low back pain and questions about the introduction of possible, therapist biases combine with mixed symptom duration among participants to make interpretation of the results difficult, particularly with regard to acute patients. Across the studies, participants with back pain of less than six weeks' duration were poorly represented. Overall, it can be said that the findings of the studies reviewed here offer limited support for the effectiveness of cognitive behavioural management approaches for non-specific low back pain before it has become persistently disabling and limited support for a role for group CBT in preventing long term disability.

4.6. Self care enhancement

A cognitive behavioural intervention which differs in its emphasis is one that is designed explicitly to promote self management by those with non-specific low back pain. Self care is considered to be an important ingredient for the successful management of non-specific back pain (von Korff et al., 1998). While most research has focussed on encouraging better self management by people who are suffering persistently disabling, chronic pain (Buenaver et al., 2006), two studies, both in the U.S.A., have reported interventions designed to enhance self care by non-specific back pain patients in the earlier phases. The first study considered here (Damush et al., 2003) enrolled patients with a current back pain episode that had lasted less than 12 weeks, although many

participants had a history of recurrent, acute episodes. The second study (Moore et al., 2000) purported to enrol sub acute back pain patients, however, the length of symptom duration for the recruits to this study is not clear.

Damush et al. (2003) reported that a self help programme for low income, urban, primary care patients with acute low back pain significantly improved functional status, mental functioning, self efficacy to manage symptoms and time spent in physical activity at 12 months. Back pain related fears were significantly reduced at 12 months compared to usual care controls. Although participants were enrolled with back pain that had lasted less than 12 weeks, many had a history of back pain episodes persisting, on average, for seven to eight years. Some three quarters of recruits were female and 59% were African American.

The intervention programme consisted of three, professionally led, self help classes held at local health centres, in addition to usual care. The classes were based on CBT and aimed to improve self management of non-specific low back pain by enhancing self efficacy beliefs and increasing participants' use of social support. In addition, intervention arm participants received follow up telephone calls, where possible, throughout the study period. The self help programme was developed after holding focus group sessions with the target population, in which identified barriers to joining the proposed research included transport difficulties, time constraints and work and childcare issues (Damush et al., 2002). It was reported that the focus group participants also expressed frustration with the recurrent nature of their back pain and disappointment with the inadequacy of available treatments.

Notwithstanding the focus group findings and the efforts by the researchers to make the programme suitable for a socio-economically vulnerable population, the intervention had high rates of non-adherence and repeated adjustments were made to the programme's planned delivery. Of the 106 participants randomised to the group sessions, less than one third attended at least one class. Programme participants differed from non-participants only in terms of being older, poorer and not being in paid work. In the first adjustment to the planned intervention, non-attendees were

sent the class materials by post and telephoned. Subsequently, non-attendees were posted the class materials along with audiotapes of the classes and a cassette player. In a final adjustment, some participants were offered individual sessions at their local health centre, arranged at a time to suit the participant. In summary, 28.3% of intervention arm participants attended at least one of the three, scheduled group sessions; 62.3% received the intervention by posted audiotapes and class materials or in an individually scheduled appointment; and 9.4% received no intervention. This third group consisted of those who could not be contacted at all by telephone or who had moved following enrolment without leaving a forwarding address (Damush et al., 2002). Twelve month follow up data were available for 66% of the total study participants (Damush et al., 2003).

The adjusted, self help intervention in the study by Damush and colleagues, in which the majority of participants received programme materials at home by post, rather than taking part in the planned, group sessions, indicates that CBT based materials suitable for independent use at home may be a practical method of self help programme delivery. Reported benefits of the intervention included significant improvements in physical and mental functioning and self efficacy beliefs relating to symptom management. Nonetheless, the positive findings from this early, self help intervention study should be interpreted with caution due to the large loss of participant data by the 12 month follow up. In addition, it is noted that the researchers used the Arthritis Impact Measurement Scale as a main outcome measure, which is validated for use in arthritis patients and not in non-specific low back pain patients.

An earlier study, also in the U.S.A., investigated a brief intervention to enhance self care among non-specific back pain patients with pain of varying duration (Moore et al., 2000). This self help intervention was devised for sub acute back pain patients and consisted of two, two-hour sessions facilitated by professional psychologists with expertise in pain management. The programme was designed to foster favourable attitudes to self care, to reduce pain related worry and fears, to encourage making personal plans for pain management and to improve pain and functional outcomes. The group sessions were supplemented by educational materials. Those assigned to the control group received usual care and a book about back pain. The authors did not report the

duration of the patients' back pain on enrolment, however, potential recruits were approached between six to eight weeks after consulting a primary care physician for back pain. Approximately 50% of participants reported having pain for more than half of the days in the previous six months.

Overall, the self help intervention was found to be effective in decreasing back related worries, pain intensity and fear avoidance beliefs. It was also successful in improving functioning and in favourably influencing patients' self care attitudes. Many of the between group differences reported at three, six and 12 month follow up were statistically significant but nonetheless modest. The researchers reported that 80% of those randomised to the self care groups attended both sessions and approximately 85% of all study participants were followed up to 12 months. Participants in this research were: "... typically middle aged, well educated, employed, married and Caucasian" (p.148). Comparison with participant characteristics and programme adherence in the Damush et al. study (2002; 2003) suggests that interventions requiring personal attendance at scheduled meetings may be a particularly inappropriate format for delivering self help interventions to poorer, less well educated members of the non-specific back pain population. An alternative interpretation might be that people with back pain symptoms of less than 12 weeks' duration may be less motivated to attend and complete a brief, self help programme, although this speculation does not on the face of it appear to be supported by the focus group patients' reported frustration with recurrent, acute back pain episodes and previously inadequate treatment (Damush et al., 2002).

4.7. Stepped care treatment model

Moore et al. (2000) discuss their self care enhancement programme in terms of the stepped care model (see Table 3) in which the least intensive, and usually least expensive, intervention is offered initially, to be followed if necessary by a Step 2 intervention for those whose symptoms persist (Pruitt & von Korff, 2002). Structured exercise or cognitive behavioural based programmes, such as the interventions by Moore et al. (2000) and by Klaber Moffett et al. (2004), would constitute Step 2 level interventions. A third level of intervention would be more complex and costly and would be reserved for people who had failed to respond to either Step 1 or Step 2 treatment

and who were at significant risk of permanent disability (Pruitt & von Korff, 2002). Referral to a multidisciplinary pain management clinic for chronic, disabling low back pain would be a Step 3 intervention.

Table 3: Adapted outline of stepped care model for back pain management by von Korff (1999)

Intensity of intervention	Focus of intervention	Provider and format
Step 1	Reassurance	GP; surgery visit by individual
Step 2	Activity increase	Psychologist/other health care professional; group or individual
Step 3	Rehabilitation	Psychologist and other health care professionals; group or individual

Von Korff (1999) proposed the stepped care treatment model for managing non-specific low back pain in primary care in the U.S.A. and it is similar to the model of care now in place in the U.K. Each ascending level of a stepped care model should apply to successively smaller numbers of back pain patients. Step 1, consulting the GP with an episode of acute, non-specific back pain, entails examination (to rule out “red flags”) followed by reassuring the patient and providing some information and advice to stay active.

In the U.S.A. it has been estimated that 20 - 30% of primary care patients will progress from Step 1 to Step 2 of the stepped care model (Moore et al., 2000). The U.K. prognosis findings presented earlier in the thesis (for example, Croft et al., 1998) also suggest that a significant proportion of non-specific, low back pain patients in the U.K. may fail to benefit adequately from brief, verbal reassurance and advice given at Step 1. Further, in the U.K., Step 2 would normally consist of referral to routine NHS physiotherapy for which there is a weak evidence base (Frost et al., 2004; Hay et al., 2005). This strongly suggests that, in addition to ongoing research into interventions aimed at diverting back pain sufferers from persistent pain and disability at Steps 2 and 3, the possibility of also improving the effectiveness of Step 1 could be actively pursued. At Step 1, the

aim would not be to identify particular, “at risk” sub groups based on adverse, psychosocial prognostic factors. Rather, it would be assumed that such prognostic factors were still in flux and that a Step 1 intervention should aim to provide non-specific low back pain patients with additional reassurance, accurate information about their condition and encouragement to consider a range of possible self management strategies as early as possible.

A single study in The Netherlands that aimed to enhance Step 1 effectiveness was unsuccessful, possibly due to inadequate delivery of the planned psychosocial intervention by GPs (Jellema et al., 2005a; Jellema et al., 2005b). GPs working in the U.K. also face severe time constraints for consultations, which would likely preclude longer investigations into individual patients' psychosocial risk factors or the delivery of more comprehensive, early back pain treatments by primary care doctors. An alternative Step 1 strategy would require to take account of this, perhaps by delivering a minimal, early intervention outside the surgery following an initial consultation for acute, non-specific low back pain. Delivering a Step 1, minimal intervention by audio CD would standardise its content and delivery and would incur minimal costs. An audio CD for home use might also be a more appropriate format for delivering a self help programme to a wider spread of socio-economic groups (Damush et al., 2002; 2003).

4.8. Summary of Chapter Four

- Dissemination of appropriate, psychosocial education and advice may play a role in improving back pain knowledge and beliefs about non-specific low back pain, at a population level and an individual level
- Its impact on employment related and clinical outcomes is less clear
- Limited evidence supports cognitive behavioural based interventions at Step 2 of “stepped care” for non-specific low back pain, including some support for group CBT interventions at Step 2

- There is emerging evidence to begin to challenge the U.K. model of care for acute, non-specific low back pain of assess, advise and wait, particularly with regard to addressing psychosocial factors
- A significant proportion of primary care patients may fail to benefit from the current Step 1 in the stepped care model, which is to assess and reassure; alternative, practicable strategies to enhance Step 1 care should be sought
- It may be deduced from the limited, available evidence that a Step 1 intervention should not attempt to modify one, particular psychological variable, such as fear-avoidance, but could focus on education, encouragement of activity and enhancement of self care
- A single study that has investigated improving existing treatment at Step 1 (with a minimal, psychosocial intervention delivered by GPs) showed no effects, possibly due to inadequate intervention delivery
- A standardised, inexpensive, Step 1 intervention could be delivered by audio CD
- An audio CD for home use might be a more appropriate delivery format for a range of socio-economic groups

5. Chapter Five. Pilot evaluation of self help CDs.

5.1. Introduction

This chapter describes the design and production of two audio CDs developed to encourage the active self management of early, non-specific low back pain. Selected extracts from the audio CDs, one of which focusses on progressive muscular relaxation techniques and one of which focusses on exploring links between emotions, thoughts and behaviours, are presented in the text to illustrate the contents of the self help programmes. A pilot evaluation of the new intervention materials is reported. The main objective of the pilot evaluation was to assess the acceptability of the self help audio CDs to potential users – whether the format and contents were easy to use and to understand and if the programmes were deemed to be satisfactory by listeners who had early, non-specific low back pain. A further objective was to inform the planning for a subsequent, randomised, controlled trial of the effectiveness of the audio CDs for early management of non-specific, low back pain.

5.2. Design, content and production of self help materials for early, non-specific back pain

This section gives a detailed account of the processes involved in planning the format and contents of new, audio CDs designed to enhance self management of early, non-specific back pain. It then describes how the materials were produced.

5.2.1. Design considerations

The dearth of investigations into enhancing Step 1 of stepped care (von Korff, 1999) for non-specific low back pain, despite ongoing back problems for many who visit their GP with back pain, suggested that the setting for a future study of the effectiveness of an early back pain intervention should be in primary care. Hence a pilot evaluation of the new intervention materials was planned for a primary care setting, consistent with the view in favour of primary care interventions for back pain expressed by Linton (2002) and the identification of the GP surgery as a preferred source of support for self care (DoH, 2005b). The format of the intervention – audio CD - was chosen to

maximise the practicability and accessibility of a primary care intervention. An audio CD costs very little to reproduce, requires virtually no additional consultation time from the GP who dispenses it, is small and light for patients to carry, may circumvent potential, literacy problems (at least, in part) and needs only audio CD playing technology to be heard. Such technology is widely available in one or more forms to a large majority of the U.K. population. An audio CD would not be an appropriate format for patients with moderate or severe hearing difficulties, however.

It was thought practicable for GP surgeries to have available a non-specific back pain intervention that could be administered without introducing resource implications in terms of the availability of appropriately trained staff and associated financial costs. Further, for the purposes of assessing the interventions' effectiveness, it was considered desirable to have standardised self help programmes on CD; an invariant, pre-recorded intervention would circumvent the introduction of confounding factors from deviations from the intended, programme contents or from variations in delivery style by different therapists in a face to face setting.

The interventions were designed within a biopsychosocial framework, drawing on an extensive pain management literature and especially the CBT literature, both of which have been reviewed earlier in this thesis. Given the lack of good evidence about what works for whom (Turk & Flor, 2006; van Tulder et al., 2003) and the suggestion that personal preference might influence intervention adherence and outcome (Goossens et al., 2005), it was decided to design and produce two intervention options. Each option emphasised different components of established CBT programmes for pain management, specifically, muscle relaxation (Turk et al., 1983) and cognitive restructuring skills (Turk, 1997). It was speculated that a potential user might have prior experiences and idiosyncratic preferences that would make either the prospect of learning progressive muscular relaxation or of focussing particularly on their cognitions differentially appealing and thereby influence motivation to take up one or other programme. Exercising a choice could also support feelings of taking control, which, combined with any increase in motivation, could have an impact on the rates for completing the self help programmes and on

their effectiveness. In other respects, however, the researcher aimed to design two programmes that were broadly similar.

Each is a self contained, audio programme that can be used at home. Both self help programmes take approximately 25 minutes a day over a three week period to complete. Although evidence is lacking on the best length of a CBT based, self help intervention for acute low back pain, focus group data from Damush et al. (2002) suggest a three week intervention period could be acceptable to many early back pain sufferers, including those in challenging socio-economic circumstances.

In accordance with the available evidence for the effectiveness of education (for example, Engers et al., 2008; Waddell et al., 2007), of CBT for the management of chronic pain (for example, Morley et al., 1999) and preliminary evidence to support CBT for back pain before it has become persistently disabling (for example, Linton et al., 2005), both sets of intervention materials were based on educational information about the condition of non-specific back pain, combined with some skills and techniques for enhancing self management learned from CBT (Turk & Flor, 2006). However, to avoid patients' possibly confusing a minimal, self help programme with a full, therapeutic course of CBT delivered face to face by professionals – which, it might be speculated, could influence patients' attitudes to future CBT programmes if these were to be prescribed for them - it was thought preferable not to label the self help interventions explicitly as “CBT”, despite their foundations in this evidence based, therapeutic approach. The chosen titles, “Using Relaxation Skills” and “Using Thinking Skills”, tried to emphasise the educational and skills based approach of the programmes rather than overtly heralding a psychological approach. This was also an acknowledgement of anecdotal evidence that some back pain sufferers may interpret references to psychological aspects of pain management as a dismissal of their physical pain; health professionals' references to psychosocial factors may inadvertently convey to sufferers that their experience of back pain is held to be “all in the mind”. Goldacre (2007) writes that, just as risk factors for a “niggle” turning into chronic back pain are personal, psychological and social, so should interventions be. However, he goes on:

“The finer distinctions between concepts that doctors use to describe the multiple interactions between a person, their illness and society have little purchase in the crudely dualistic world of popular culture, and sometimes it can seem that there is a hypersensitivity to anyone even mentioning psychosocial risk factors or interventions. In a culture where 'psychosocial risk factors' can be heard as 'psychosomatic illnesses', and with a popular media where 'psychosomatic' simply means 'imaginary' and 'malingering' (*Psychosomatics* 2004; 45:287-90), these negotiations will never be easy.” (p. 801)

It was hoped that by choosing more neutral sounding, descriptive titles for the self help programmes, this would avoid arousing potential resistance to psychological approaches to what might, at least initially, be perceived by the back pain sufferer as an exclusively physical and “medical” problem.

5.2.2. Contents

The rationale for the contents of the audio CDs was that skills learned for pain management in CBT programmes might usefully be applied to managing pain before it had become chronic and disabling. The choice of CBT components also reflected the evidence reviewed in Chapter Four, which indicated that targeting a specific psychosocial factor, such as fear avoidance, was unlikely to be a productive approach with an acute population, for whom psychosocial risk factors might still be in flux. The contents were therefore based on components of established, CBT pain programmes. For example, the programme of CBT sessions for spinal pain used by Linton and colleagues included education about pain, relaxation training, problem solving skills, activity scheduling and consideration of cognitive appraisals and beliefs (Linton & Ryberg, 2001).

Suggestions and comments on the draft scripts for the audio CDs were gratefully received from Dr. J. Kunkler, an Edinburgh based, NHS clinical psychologist with expertise in pain management and CBT.

Both audio CDs begin by giving the same, factual information on the condition of acute, non-specific low back pain, with reassurance in the absence of serious spine disease that “hurting does not equal harming” and advice on pain control. The latter includes some simple, home based

approaches to pain alleviation, such as applying a heat pack to the back (Chou et al., 2007). The common introduction to both programmes emphasises the benefits of physical activity (Roland et al., 2000) and also gives information on the importance of pacing activities. Pacing refers to a controlled, gradual and gentle build up of exercise tolerance, an important strategy for avoiding pain flares that may be induced by sudden, inappropriate increases in physical demands on the body. The efficacy of physical activity has been demonstrated in a systematic review of interventions for both acute and chronic low back pain (van Tulder et al., 1997). Exercising has physiological effects, for example, strengthening muscles, and may also impact on functioning indirectly by modifying pain related beliefs (Mannion et al., 1999). Evidence from a range of populations supports an association between physical activity and both physical and mental health benefits, including improved general and health related quality of life, increased functional capacity and improved mood states (Penedo & Dahn, 2005). The role of everyday postures – when sitting, standing, lifting and sleeping – is also addressed on the CDs.

Both CDs aim to promote reassurance for non-specific back pain sufferers and to encourage positive attitudes towards active self care. The goal for both programmes is to enhance self management for living with episodes of acute back pain and to prevent the situation from deteriorating.

The following are extracts to illustrate the introductory contents of the “Using Relaxation Skills” and the “Using Thinking Skills” audio CD programmes. Copies of both audio CDs are available in Appendices 1 and 2.

“The reassurance from your doctor that your back pain is not caused by a serious, spine disease is one of the most important things for you to take on board. This doesn’t mean your back pain isn’t real. It is and it hurts! But, if you are worrying that your back pain is something more ... don’t be afraid to seek further reassurance from your GP. After all, if you keep unnecessary worry to yourself, the pain you have is likely to seem even worse and be even harder to cope with.”

“If you are used to sleeping propped up on lots of pillows, try sleeping with fewer pillows... Experiment to find out what works best for you. It may not be what you are used

to. Some people find lying on their back with a pillow, or two or three pillows, under their knees is a comfortable, night time position. A good night's sleep and a comfortable back when you wake in the morning are definitely worth experimenting for."

"Don't be tempted to overdo it in the early days, and don't give up because it's sore. Remember, you are not causing back damage by gentle movements. The phrase to remember is, 'Hurting does not equal harming'."

"If, after exercise, you suffer a significant change for the worse in your back pain and that increased pain does not resolve, you are probably overdoing it! If your back's soreness continues or only temporarily becomes mildly worse, you'd be better to persist. Recall the phrase, 'Hurting does not equal harming'."

"Because everyone is different, it has to be a case of finding out what helps you. Warming the painful area – by placing a covered, hot water bottle at your back, or even just taking a warm bath or shower – can be soothing. On the other hand, some people find more relief from a cold pack, or from alternating a cold and a hot pack. To make your own cold pack, you can wrap a bag of frozen peas in a towel and place that at your back, for five – up to a maximum of 10 - minutes at a time."

The "Using Relaxation Skills" CD programme continues with an introduction to progressive muscular relaxation (Jacobson, 1938). One model of the relationship between back pain and muscular tension is that pain is exacerbated by overly tense muscles that accompany ineffective coping with major and minor stresses (Arena & Blanchard, 2001). Previous research suggests that learning to carry out progressive muscular relaxation can positively influence indicators of both physiological and psychological stress (Kerr, 2000). "Using Relaxation Skills" gives a short description of the rationale for using progressive muscular relaxation for back pain, exercises to practise full relaxations, plus encouragement to carry out brief, mini relaxations of particular muscle groups that may be prone to becoming overly tense during a normal day (Lichstein, 1988). It is recommended that the first relaxation exercise should be practised at least once a day for a week before moving on to the second exercise in the second week and, finally, the third relaxation exercise in the last week. Users of the programme are encouraged to persist with progressive muscular relaxation; people may find it becomes easier with practice and some may not experience the full benefits until regular relaxations have been carried out over a period of time (personal communication, Dr. J. Kunkler). No special place or equipment is needed to carry out the

CD relaxation exercises and there are practice sessions suitable for carrying out while sitting up and while lying down.

The following is an extract from “Using Relaxation Skills”, which is available as an audio CD in Appendix 1.

“This exercise aims to reinforce learning to recognise the different feel of tense muscles and relaxed muscles. Sit yourself comfortably in your chair. Check your back and head are well supported. If you’re wearing anything tight, loosen it. Take your shoes off if you want to. Place both feet flat on the floor, slightly apart. Allow your arms to rest at your sides, with both your hands resting in your lap, one on each thigh. Or you can place a pillow or a cushion or two on your lap and rest your forearms on that if you find that more comfortable.

Keep your breathing regular and unhurried. Try to breathe through your nose. As you breathe, notice the light, comfortable balance of your head on your spine... feel your arms resting... notice the gentle rise and fall of your tummy as you breathe in...and out... in...and out... Notice the feel of the chair as it supports the weight of your body... Feel the weight of your feet against the floor...

Start at your feet... curl up both feet, then uncurl them and point your toes up in the air with your toes splayed out ... and hold your feet like that... make the feet work, as far as is comfortable for you, to hold that rigid position... and now relax the feet... Let them rest, as they were, against the floor...Think about any remaining tension in your feet starting to ease away...

Now squeeze all of the muscles in both of your legs. Feel the increased tension as you tighten up your calf muscles, and your thigh muscles... keep squeezing, just so far as is comfortable... and now release that increased tension... Can you allow your calves and thighs to be a little more relaxed?

Now tense your stomach muscles by pulling your front in and up, making your front harder... Imagine making your front harder as if you were expecting something to hit your front... hold it... and now relax that again... Feel all the stomach muscles go from harder to softer. Keep your breathing regular and calm.

Very, very gently, arch your back. Squeeze your shoulder blades together and make as if you were trying to slide your shoulder blades down your spine... Hold that tension in your back ... the whole surface of your back should be harder now... and let that go... Still thinking about your back, can you let your back muscles soften a little further still? ... Let the chair support your softer back.

Shrug your shoulders, bringing them up and in towards your neck... very, very gently, start to press your head back into the chair, using your neck muscles.... And relax again... Check your shoulders and neck for any remaining tension... Can you feel it starting to ease away? Let your shoulders and neck feel softer.

Stretch out both arms and hands, spread your fingers wide and back, and squeeze... every muscle in your hands and all along your arms is working now... hold...and relax again. Return your hands to rest in your lap or on your pillow. Can you allow yourself to let your arms and hands go a little more limp? Your hands are resting, softly, again.

Squeeze your forehead into a frown, with your eyebrows lowered and knitted together. Squeeze your jaws together as if you were biting. Tense up your cheeks, squeeze your lips into a purse, and hold the grimace... and now start to let it go.... Think about letting every little muscle in your face relax a little further, so your whole face can be smoother and softer ... Can you let your mouth soften more? ... Can you let your eyes soften more? ...Can you feel your forehead starting to smooth out?

Remember to keep breathing, calmly and steadily... Be aware of the feeling of soft, relaxed muscles throughout your body... the softness of your face...

In your own time, when you are ready, you are going to stand up. Don't rush to a standing position. Have a gentle stretch in your chair...wiggle your hands... shake your arms. Wiggle your feet... and shake your legs... Gently shrug your shoulders again and let them fall ... When you are ready, return to a standing position. Well done."

The alternative programme, "Using Thinking Skills", continues by talking about the connections between thoughts, feelings, physiology and behaviours. The exercise for Week One in this programme is to keep a daily record of the worst and best times of each morning, afternoon and evening, with participants noting what they were doing, feeling and thinking and the intensity of their back pain at each time. This is designed to build up a written record on which participants can reflect, helping to illustrate what helps them to manage their back pain more successfully and what makes it harder for them to do so. Week Two teaches a structured, step by step approach to problem solving and to planning a paced approach to increasing physical activities. There are example worksheets and homework worksheets for participants to use to solve whichever problem or problems are relevant to them and the management of their back pain. Week Three of "Using Thinking Skills" focuses on identifying and challenging unhelpful thoughts, for example, catastrophising and fear avoidance beliefs. It is explained that the thinking-feeling-doing circle can become a "vicious circle". To prevent or break out of a such an unhelpful circle, it is necessary first to learn to recognise when one is having unhelpful, extreme thoughts and then to recognise that it is not inevitable that one has to act on them. Again, the audio CD track is supplemented by example worksheets and by homework worksheets for participants to try to complete themselves during the last week. All the worksheets for the "Using Thinking Skills" programme are available in Appendix 3.

The following are excerpts from “Using Thinking Skills”, which is available as an audio CD in Appendix 2.

“Thinking, feeling and behaviour are all connected within each person, even if in our day-to-day lives we are often unaware of it. It’s useful to start to recognise and understand those connections, however, because we can use that knowledge to our advantage - not to cure back pain but to make it easier for ourselves to manage living with it.”

“Unfortunately, we can’t just tell ourselves NOT to think about something and expect that to work. If anything, the more we tell ourselves not to think about a particular thing, the more we think about that very thing! Rather, what we can do is try to make sure our focussed attention is “used up” by keeping it busy elsewhere. Most of us have at some time been engrossed in a favourite film, or so concentrated on a piece of work that we don’t notice time passing, or had that feeling of being “lost” in a good book, or swept up in the excitement of a sporting event. When the focus of our attention is on activities such as these, it is diverted from everything else, including the sensation of pain.”

“The important thing to remember when writing out your own plan is to be realistic. Start off with a daily target you are confident you can achieve. It’s not a competition. You will have your own starting point, depending on your own, current fitness level and your pain severity, and you will have your own targets and your own time scale for reaching them.”

“The advantage of writing out a weekly plan for yourself is that you can see a clear path to follow. Each day, you know exactly what you aim to do that day, and that’s what you do. The plan guides you so you don’t do much more one day, just because you’re feeling particularly good that day, nor do you skip a day because you’re feeling worse. Remember, your back feeling sore does not mean that you are damaging it. A plan also gives you an accurate record of the real progress you are making, which can give just that little bit of extra encouragement needed on those days when you are not feeling so good.”

“If we have thoughts that are extreme and unhelpful, these are called “thinking errors”. They are so-called because errors arise from our making assumptions, or coming to conclusions, without good reason or without adequate evidence. There are some common thinking errors. Surely every one of us has experienced one or more of these at some time? See if you can recognise any as we go through this list.”

“So, how can we spot when we are making thinking errors? It is not easy at first. We tend not to examine our thoughts, at least, we tend not to check our thoughts for their accuracy. It does become easier with practice, however, and if one is prepared to be part detective – seeking clues to alert one to possible thinking errors – and part scientist – carefully assessing the suspect thinking.”

“One clue to look out for is a change in your behaviour. If you find yourself doing something differently, say, not going out when you normally would, ask yourself: what were the thoughts that were going through my mind then? Another clue to watch out for is a sudden worsening of mood. If you notice your mood changing, for example, you suddenly feel more fearful, angry or miserable, ask yourself: what were the thoughts that were going through my mind just before I felt like that?”

5.2.3. Production

When the scripts for “Using Relaxation Skills” and “Using Thinking Skills” had been finalised, they were recorded, read by the author, onto master audio CDs by a recording studio technician at Queen Margaret University. Subsequently, copies of each programme were made from the master recordings. Each CD was labelled with its title and a printed, cardboard insert giving the individual track numbers and track titles was placed in each CD box. Copies of the example worksheets and homework worksheets to accompany the “Using Thinking Skills” audio CD were collated and stapled into A4 booklets for distribution with the “Using Thinking Skills” CD. Similarly, diaries to record daily use of both the “Using Relaxation Skills” and the “Using Thinking Skills” programmes and to rate the users' satisfaction with them were printed out and stapled into A4 booklets. See Appendix 4 for copies of the contents of the accompanying booklet.

5.3. Planning a pilot evaluation of the new intervention materials

Help to recruit local, GP practices for a pilot evaluation of the audio CD intervention materials was offered by the Lothian and Borders Primary Care Research Network (LBPCRN) after a series of meetings at which the project was discussed with the organisation's acting Network Co-ordinator. Unfortunately, the offer of practical help with GP recruitment was subsequently unexpectedly withdrawn due to a change of policy within the organisation. The acting Co-ordinator wrote:

“We are having severe difficulties recruiting practices into studies which is due in part to the workload of GPs and priorities that have been placed on GPs' work. As a direct result we are having to prioritise the assistance we can offer, focussing on larger funded studies which contribute to the Support for Science agenda of the Scottish Office.” (personal correspondence)

The difficulties with recruiting GP practices referred to by the LBPCRN were related to the introduction in Scotland of a new, Government contract with GPs and to associated changes to their working practises, which coincided with the timing of the thesis research. As a consequence of the LBPCRN now being unable to assist with GP recruitment to the thesis study, the researcher decided to use personal contacts with GPs in Edinburgh to identify a practice that might be willing to participate in the initial phase of the thesis research.

The Muirhouse Medical Group (MMG) is a primary care practice with seven partners and a patient list of some 11,000. It is based in the north of the city of Edinburgh and covers a range of residential areas, from socio-economically deprived housing schemes to relatively affluent neighbourhoods. The former predominates. After a personal approach to one of the MMG doctors, the partners at this surgery consented to have a short presentation about the proposed, early back pain intervention study during one of their weekly, lunch time meetings. Subsequently, this practice agreed to participate in an initial evaluation of the new, intervention CDs. Discussions following the presentation to the partners allowed the doctors' input to be incorporated into the design of the pilot evaluation. For example, it was suggested it would fit with the daily workings of the busy practice to have a "post box" at the surgery reception. It was agreed that the doctors would identify potentially eligible back pain patients during routine consultations. Identified patients could then use the post box to indicate whether they were interested in being contacted by the researcher with further, detailed information about the study. It was agreed by the partners that the researcher could empty the post box at the surgery several times a week during the recruitment period.

5.3.1. Ethical and NHS management approvals

Before embarking on the CD pilot evaluation involving NHS patients at MMG, an application for ethical approval was submitted to the Central Office for Research Ethics Committees (COREC). The application was approved at a meeting on April 6, 2005 of the Lothian Local Research Ethics Committee (Appendix 5). The researcher attended the meeting to answer questions in person from the committee members. Ethical approval was granted subject to the Principal Investigator

obtaining management approval from the relevant NHS body. Accordingly, an application for management approval was sought from the NHS Lothian Primary Care Organisation and this was approved at a meeting of its Research and Development Committee in July 2005. Although the Research and Development Committee granted full approval to the proposed evaluation of the back pain CDs, it was noted in its response that committee members had expressed some reservations based on the likelihood there would be “difficulty in recruiting”. NHS management approval was given with the condition that the Principal Investigator obtained an Honorary NHS Contract before beginning an evaluation of the intervention materials by NHS patients. An Honorary NHS Contract was therefore requested and this was received by the researcher in October, 2005.

Despite there being no amendments nor re-submissions required at any stage of the process, obtaining full ethical and NHS management approvals took some eight months in total and concerns about likely, future delays due to difficulties with recruiting GPs and GP patients were flagged up before the CD pilot evaluation started.

5.4. Pilot evaluation of the audio CDs

The following section describes in detail how the pilot evaluation of the face validity of the CDs was carried out and reports its findings.

5.4.1. Objectives

The principal objective of the pilot evaluation was to assess whether the new, audio CDs for home use were easy for primary care, back pain patients to use and to rate the users’ satisfaction with the self help programmes. Secondary objectives were to assess the practicability of using a GP setting for an effectiveness study of the self help CDs and to pilot proposed outcome measures for an effectiveness study investigating the validity of the content.

5.4.2. Overview of the CD pilot evaluation study

A pilot evaluation of new, self help, audio CDs for early back pain was carried out in an Edinburgh GP surgery. Six patients with non-specific low back pain that had persisted between three and eight weeks consented to trial two, alternative CDs to promote better self management of acute, non-specific low back pain. Three participants were allocated to a “Using Relaxation Skills” programme and three were allocated a “Using Thinking Skills” programme. Participants kept a daily diary while they completed the audio CD programmes at home to record their daily, programme use. They were also invited to meet individually with the researcher at the end of the intervention period to give any additional feedback they wished. One CD pilot evaluator took four weeks to complete the “Using Thinking Skills” programme, rather than three, and one completed only two weeks of the programme. “Using Relaxation Skills” was completed in three weeks by all three CD pilot evaluators. All participants nonetheless expressed some satisfaction with the CD self help programmes and reported they had found them helpful to some degree. Two participants who had been allocated the “Using Thinking Skills” audio programme volunteered in their feedback that they would have preferred to select which of the two audio CDs they had used. The “Using Relaxation Skills” programme would have been the preferred option for these participants. The three who were allocated the “Using Relaxation Skills” CD also indicated this was the programme they would have selected had they been offered a choice. The self help, audio CD programme, “Using Relaxation Skills”, may have wider appeal to early, non-specific back pain patients.

5.4.3. Methods

Recruitment: After obtaining ethical and management approvals and an Honorary NHS Contract, the researcher took written, informed consent from the GP partners at an Edinburgh surgery. The participating GPs then identified potentially eligible patients during routine, back pain consultations. The patients were given brief, verbal information about the CD evaluation study and a copy of the Participant Information Sheet and Consent Form to take away with them (Appendix 6). They were invited by the doctor to leave their names and telephone numbers in a study post box at the surgery reception desk if they wished the researcher to contact them to discuss the study further.

Alternatively, interested patients could make direct contact with the researcher, whose contact details were on the Participant Information Sheet (Appendix 6).

The inclusion criteria for taking part were:

- aged between 20 and 65 (non-specific low back pain is less common in younger adults, while older adults are more likely to have concurrent health problems that may be liable to confound findings)
- written, informed consent
- access to a CD player at home and a telephone
- acute, non-specific low back pain that has persisted for at least two weeks, either new pain or recurrent acute pain (many acute episodes of back pain may be expected to resolve spontaneously within a fortnight)
- able to read and write English (both interventions, and particularly the “Using Thinking Skills” programme, and the outcome measures rely on competency in the English language)

The exclusion criteria were:

- demented; current diagnosis of clinical depression; painful, chronic illness (these conditions may be expected to impair ability fully to understand and complete the interventions and to confound results)
- non-English speaking

- specific low back pain diagnosis, for example, infection, neoplasm, metastasis, osteoporosis, rheumatoid arthritis or fracture (the research is concerned with the common condition of non-specific low back pain for which no organic pathology is evident on medical examination)
- non-specific back pain of less than two weeks' or more than nine weeks' duration (the interventions are self help programmes that take three weeks to complete; pain that has persisted for 12 weeks or more may be temporally categorised as chronic, rather than acute, back pain)
- previous participation in a back pain management programme, for example, physiotherapy with a CBT component (some physiotherapists are now trained to offer psychological intervention in addition to manual physiotherapy following referral by a GP; prior experience of psychological approaches to pain management may bias expectations and confound findings)
- current enrolment in other medical research (to avoid the burden of multiple research participation)

There was no provision for translation or the use of interpreters. Learning CBT based skills using self help materials in English requires personal fluency in the language. Translated materials would require to be validated before any claim for equivalence could be made. The costs of producing intervention materials to be piloted in a range of languages or of using interpreters would have been prohibitive given the scale of PhD research and available resources. Further, the majority of patients in the catchment area of the participating GP surgery were known to have English as their first language.

Over six weeks, there were 34 expressions of interest in the pilot evaluation from 18 women and 16 men. Seven potential participants who had left their details could not be contacted by telephone, despite repeated attempts. Ten were ineligible: one had no telephone, three had back pain of more than nine weeks' duration; two were older than 65 years, two people's back pain had resolved; one had subsequently developed neurological signs; and one was unable to read. A further 10 potential recruits declined to participate after discussing the study on the telephone. Four felt unable to make trips for appointments with the researcher due to the intensity of their back pain; two said they were too busy to undertake a self help programme at that time; and four declined without giving any specific reason. One participant did not attend for an initial appointment that had been arranged by telephone. Subsequent attempts to contact him again by telephone elicited no response.

Participants: Following the initial telephone contact from the researcher, based on expressions of interest in the post box, six women were enrolled at face to face meetings at Queen Margaret University. At these meetings, the researcher confirmed the participants' eligibility, discussed what was being asked of participants and answered any questions before taking the individuals' written, informed consent. One participant had a first episode of low back pain and the other five were experiencing recurrent pain. In each case, the current episode of back pain had lasted between three and eight weeks when the participant joined the research. Levels of educational attainment ranged from school leavers with no formal qualifications (two participants), to vocational qualifications from further education colleges (three) to university degree (one). Ages ranged from 25 to 62 years. All reported that they had been advised by their GPs to take painkillers and to try to keep active. Two had been referred for NHS physiotherapy and were awaiting notification of their first appointments. Neither began their physiotherapy sessions before the end of the four week, pilot evaluation period.

Randomisation: Enrolled participants were randomised to receive either the "Using Relaxation Skills" programme or the "Using Thinking Skills" programme, using a computer generated list of random numbers to allocate three participants to each intervention group. While it was recognised

that personal preference for one or other programme might play a role in intervention adherence and outcome, an assumption that choice would be of importance to participants was considered to be premature at this stage of the research. Relevant feedback on programme preferences would be sought from those evaluating the new CDs. Here, for the purposes of evaluating both, new interventions, it was important that both the audio CDs were tried out.

Intervention: One of two, self help audio CDs, giving information on non-specific low back pain and either training in progressive muscular relaxation or training in CBT based pain management skills. Each programme required listening to one audio session at least once at the start of each of the three weeks of the programme. Daily skills practice throughout each programme was strongly recommended. The audio CD intervention was in addition to usual GP care in all cases.

Measures: The primary outcome measure was a self report diary of intervention implementation and the user's satisfaction with the programme (Appendix 4). Secondary outcome measures were the Roland & Morris Disability Questionnaire (Appendix 7), the SF-12v2 Health Survey, a self reported measure of pain intensity and the Patient Health Questionnaire (Appendix 8). These are described more fully below.

Each intervention CD was accompanied by a daily diary to monitor programme use and satisfaction. The diary provided daily use and weekly satisfaction rating scales and a page for free text if participants wished to write their own comments. Participants were also encouraged to give verbal feedback during a post intervention meeting with the researcher, four weeks after recruitment. The diaries and verbal comments provided information on how the programme had been used at home, how satisfied users felt with it and whether they had encountered any problems or had any other comments or suggestions for improvements to the programmes.

In addition, the pilot evaluation was used to pilot proposed outcome measures for a planned study of the programmes' effectiveness. Unlike prognostic assessments, in which questions of specificity and sensitivity are of importance, the criteria for appropriate measures in back pain research

concern utility (is the measure useful in this setting?), reliability (is it a dependable measure?), validity (is it measuring what it purports to measure?) and, of importance in a study design with assessments before and after an intervention, responsiveness (can it detect changes over time?). Ostelo et al. (2008) recently published a report on interpreting changes in the scores of pain and functional measures. The report is part of an international move to raise the methodological standards of back pain research and to increase the usefulness of individual studies by making them comparable to one another for statistical meta analyses (Dionne et al., 2008; Ostelo et al., 2008; van der Windt et al., 2008). In accordance with the current, international recommendations for researchers, which are derived from a combination of reviews of the literature, expert witnesses and workshops (for example, the "VIII International Forum on Primary Care Research on Low Back Pain", Amsterdam, 2006), this research employs approved back pain study measures that address a recommended range of outcomes. Pain intensity – the level of pain experienced by a person – and pain affect – how much that person is suffering – are not wholly independent of each other but there are conceptual and statistical differences in their measurement. Psychometric properties for pain affect measures are described in Box 3. It is recommended that back pain research instruments should cover back pain specific functioning and general health and quality of life in addition to self reported pain intensity (Mannion et al., 2007).

Intervention effectiveness will be measured by the Roland & Morris Disability Questionnaire (RDQ) (Roland & Morris, 1983; Bombardier, 2000), a reliable, validated, self-completed, 24 item assessment to measure back pain specific, functional limitations in daily living. The questions are derived from the Sickness Impact Profile, with the addition of the phrase "because of my back", and cover a range of items, including mobility, self care, appetite, irritability and sleeping. Von Korff & Saunders (1996) report that an RDQ score of 13 or more is associated with significant disability and poor outcome. The RDQ response is dichotomous; respondents indicate whether or not statements are true for them in the last 24 hours. Positive responses are summed to give a total score, with a higher score indicating greater functional disability. A change of five points or greater on the RDQ or a 30 per cent change from the baseline score are considered to be of clinical

significance, according to recent, international guidance to back pain researchers (Ostelo et al., 2008).

Examples of items from the RDQ are: I walk more slowly than usual because of my back; Because of my back, I have to hold on to something to get out of an easy chair; Because of my back, I try to get other people to do things for me; My appetite is not very good because of my back pain; I sleep less well because of my back; Because of my back pain, I get dressed with help from someone else. The RDQ is freely available on the Internet (<http://www.rmdq.org/>). See Appendix 7.

Box 3. Psychometric properties of instruments to measure pain affect.

Adapted from Mannion et al., 2007

Score distribution: a score distribution which shows a small percentage of respondents reporting the lowest and highest scores indicates an instrument that is able to assess the full range of severity

Reliability: internal consistency, i.e., how well the items correlate with each other and the entire scale; and test-retest reliability, i.e., consistency of scores on different occasions if no relevant changes have happened. Co-efficients (for example, Cronbach's alpha and Standard Error of Measurement respectively) should be >0.7 for reliable interpretation of group change and >0.9 for reliable interpretation of individual change. Reliability is a necessary but insufficient condition for validity

Validity: whether the instrument measures what it purports to measure (influenced by reliability, the constructs in its contents, etc.). Usually assessed by measuring correlations between the instrument's scores and scoring found for conceptually closely related or clearly unrelated variables on other instruments

Responsiveness: sensitivity to relevant changes that have occurred. Usually assessed by means of effect sizes (Cohen's d), where $d \geq 0.8$ is considered large, 0.5 to 0.8 moderate and 0.2 to 0.5 small

Generic health and well being will be assessed by the validated SF-12v2 Health Survey (Ware et al., 2002). It was developed as a shorter, quicker-to-complete alternative to the SF-36v2 Health

Survey and measures the same eight health constructs. The constructs are: physical functioning; role physical; bodily pain; general health; vitality; social functioning; role emotional; and mental health. Items have five response choices (for example: all of the time, most of the time, some of the time, a little of the time, none of the time), apart from two questions for which there are three response choices (for the physical functioning domain). Four items are reverse scored. Summed raw scores in the eight domains are transformed to convert the lowest possible score to zero and the highest possible score to 100. Higher scores represent better health and well being. The standard form SF-12v2 uses a time frame of the past four weeks.

Examples of items from the SF-12v2 are: In general, would you say your health is: excellent, very good, good, fair, poor?; During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework): not at all, a little bit, moderately, quite a bit, extremely?; During the past four weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.): all of the time, most of the time, some of the time, a little of the time, none of the time? The SF-12v2 is available for a fee under licence from QualityMetric Incorporated (www.QualityMetric.com).

Pain severity will be assessed using a 100mm visual analogue scale (VAS). At either end of the horizontal line is a small, vertical mark and a verbal description ("not at all painful" at the left extremity and "extremely painful" at the right). Participants are asked to mark the line at the point that best represents the current severity of their back pain. The score is the distance measured from the left hand of the VAS ("not at all painful") to the participant's mark. The VAS is reliable and valid (Jensen & Karoly, 1993). VAS measurements correlate highly with other brief, self rated pain measures, for example, verbal and numerical rating scales, with superior responsiveness to change than scales with more limited response options (Downie et al., 1978). The VAS is widely used in published research and has the advantage of ratio scale properties for statistical analysis (Price et al., 1994). A mark less than 15 mm from the left hand side is considered to represent highly tolerable or virtually no current pain symptoms, while a difference of 30 mm between line marks on different occasions is considered to represent a clinically significant change in acute low

back pain (Mannion et al., 2007), as would a 30% shift from baseline score (Ostelo et al., 2008). Completing the VAS measure does require some co-ordination and may not be suitable in all clinical and research settings (Mannion et al., 2007), for example, it would not be appropriate for very young children.

The Patient Health Questionnaire (PHQ-9) is a screening tool for depression (Kroenke & Spitzer, 2002). It is a self administered version of the PRIME-MD depression scale, formulated from the nine DSM-IV criteria for diagnosing depression. Its nine items assess anhedonia, mood, sleep, fatigue, appetite, concentration and self-harm ideation in the past two weeks. Each item has four response choices from “0” (not at all) to “3” (nearly every day). All the scores are summed to give a total score between 0-27, with a higher score indicating greater depression. The PHQ-9 has been used as a diagnostic and a treatment monitoring tool and is increasingly used as a research instrument. It has shown good reliability, validity, sensitivity and specificity. Validity has been assessed against an independent, structured mental health professional interview, which showed a PHQ-9 score ≥ 10 had a sensitivity of 88% and a specificity of 88% for depression. It has been validated for use in primary care (Kroenke et al., 2001; Dietrich et al., 2003).

PHQ-9 scores between 5 and 9 are considered to be indicative of mild depression, of 10 to 14 of moderate depression and of 15 to 19 of moderately severe depression. A cut-off point of 20 is suggested as positive for severe depression. Potential research participants with screening scores indicating severe depression or with a current, doctor's diagnosis of clinical depression would be ineligible for the pilot evaluation and for the subsequent, effectiveness study.

Example items from the PHQ-9 are: Over the last two weeks, how often have you been bothered by any of the following problems? Little interest or pleasure in doing things; Trouble falling or staying asleep, or sleeping too much; Feeling tired or having little energy; Trouble concentrating on things, such as reading the newspaper or watching television; Thoughts that you would be better off dead, or of hurting yourself in some way. The PHQ-9 is freely available on the Internet (for example, at <http://www.patient.co.U.K./showdoc/40025272/>). (See Appendix 8.)

Procedures: Data were collected at the end of 2005. The RDQ, SF-12v2, VAS and PHQ-9 were administered to the pilot evaluation participants pre intervention (for six participants) and post intervention (for five participants). After completing the baseline measures, participants were told which audio CD they had been allocated and then given a self help programme package to take home. An appointment was scheduled for a second meeting with the researcher four weeks later. Towards the end of the first week, participants were telephoned by the researcher to address any queries and to encourage participants to continue with the programme and with maintaining their daily diaries. At the post intervention appointment, the diaries were collected and the researcher encouraged verbal feedback on using the audio CD. One participant gave feedback by telephone.

Because the primary aim of the pilot evaluation was to assess the acceptability of the programme to users, and because meaningful statistical analysis is not possible when there are only three participants per group, the scores from the outcome measures will simply be described here briefly.

5.5. Pilot evaluation findings

“Using Relaxation Skills”: The three programme testers reported they had found the relaxation, self help programme to be straightforward to follow and understand. None had suggestions for improvements. All said they believed following the relaxation self help programme had helped them, although one participant queried whether it might have made her think more about her sore back “subconsciously”:

“I started to really look forward to doing my CD. It was a chance to have some time to myself. I only listened to the first bit once – the information part at the beginning, you know – because my doctor had already told me that stuff. I’ll definitely keep on with it, for as long as I can get away with getting my husband to take the kids while I go and do my relaxation! I don’t think it has helped my pain but it has helped me. I feel better, less down. The only thing is one night I woke up with pain in my back and legs and it was almost like doing the relaxation was making me think about my back pain when I was asleep. Maybe it makes you think it about it more subconsciously? I don’t know.” (Mrs. T.)

Comments from the other participants highlighted aspects of the programme they believed had been helpful to them:

“I found doing this very useful. It’s made me think about my posture and how I work and I’ve started doing things differently. I don’t stay sitting now. I make sure I get up and walk around and it’s really helping me. And I loved doing the relaxations with the CD. I’m trying to do wee, quick relaxations throughout the day too now and that’s great. Actually, I think it’s a great package. It should be available to everyone.” (Miss B.)

“I like your voice on the CD and I liked listening to it. The programme was very easy to follow. I am definitely better at relaxing than I was before I started and my back feels better too. I was fed up at the beginning because, well, having back pain, you know, and I get it a lot. You always hear the same things, to take paracetamol and get on with it and it’s, well, it’s quite difficult. I particularly like the sitting down relaxation on the CD. I just pop the CD in and do it, even when I’m at work when I can. I’m getting more aware of when I’m getting tensed up and stiff.” (Mrs. P.)

In addition to their spoken comments, the three participants kept diaries throughout the three week intervention period to record their daily use of the relaxation CD programme and whether they believed it was being helpful. At the end of each period of seven days, participants scored their overall satisfaction that using the self help programme was helping them to manage their back pain, using a five point scale. At the end of the final week (Week Three), two participants indicated they were “very satisfied” with the “Using Relaxation Skills” programme and one indicated she was “extremely satisfied”. See Table 4.

Table 4. Diary reports of satisfaction with the “Using Relaxation Skills” self help programme.

Using Relaxation Skills	Week One	Week Two	Week Three
Not at all satisfied			
Quite satisfied	√	√	
Satisfied	√	√	
Very satisfied	√		√√
Extremely satisfied		√	√

Participants' feedback on the “Using Thinking Skills” programme was more mixed. One woman cared for her chronically ill husband and he became suddenly more ill during the CD evaluation

period. This participant telephoned towards the end of Week Three of her participation to tell the researcher about her changed domestic circumstances. The participant offered to post her diary record of her first two weeks of using the programme. She did this despite the researcher assuring her on the telephone that her immediate withdrawal from the study was entirely understood and accepted and thanking her for troubling to telephone. The following extract is from the telephone conversation:

“I’m sorry I can’t finish the programme. It’s a madhouse here, people coming and going all the time. I don’t think he’s (her husband) going to get better this time. Well. You can imagine.

I did the first week of the programme, and that was fine, it was good, and the second week. That took me more than a week to do and I won’t be able to do the last week, not now. I liked listening to you. The information on the CD was good. It’s quite good to be reminded about looking after your back. Even when you’ve heard it before, you don’t take it all in at once, do you? It did get me thinking, about my back pain, what makes it worse and that kind of thing. It’s just I can’t finish it (the programme), not now.” (Mrs. S.)

Another participant who evaluated “Using Thinking Skills” reported she had found the third week of the programme difficult. Week Three of the programme looks at identifying and challenging unhelpful, extreme thinking. This participant, who had no formal qualifications, told the researcher that the reading and writing involved in the worksheet exercises for Week Three had “put me off”, although she had enjoyed listening to the CD and reported she had managed the first two weeks’ homework exercises and had found them quite useful. In contrast to “Using Relaxation Skills”, for which the “homework” was to relax, homework for “Using Thinking Skills” consisted of completing written worksheets (Appendix 3).

“It took me longer than three weeks to finish the whole programme. I’ve had workmen in the house and also I was feeling quite down so perhaps I’ve been slow because of that. But it didn’t matter. It took me four weeks. I didn’t get on that well with the last week. I think it was because there was the work going on and I wasn’t feeling so good myself. The reading and writing for the last exercise put me off. I couldn’t concentrate, that was the problem. There was reading and writing homework for the first two parts but it was easier to concentrate then. I might have been better with the relaxation programme. I think I would have liked it better. The exercise in the first week, where you kept a diary of how you were feeling, I found that quite helpful, you know. And I liked the second week. It made me write down how I’d start taking more exercise and I’m going to do that.” (Mrs. D.)

The third evaluator was very positive about the “Using Thinking Skills” programme:

“The first week’s exercise, to my surprise, I did find patterns emerging and that’s something I can use in the future. My back is feeling better now, most days. It was certainly helpful. The problem solving exercise is very useful too. I’ve used that to look at getting more exercise into my daily routine and so far, so good! The last part really got me thinking about how I think about things sometimes and how it sometimes doesn’t help to think like that, and you can think differently. Or you can try to. I’m going to keep on with that part because there’s a lot to that. I thought the whole programme was well put together, clearly set out and very good worksheets and examples. My only comment would be that people should be encouraged to do the worksheets while they are listening to the CD, or straight away afterwards, while it’s fresh in their minds. You have a nice voice – calming. Altogether I found it an interesting and helpful programme for back pain. Thank you!” (Mrs. M.)

The diary satisfaction ratings for the “Using Thinking Skills” programme (Table 5) reflected the participants' verbal reports. Of the two who completed the whole programme, one indicated she was “quite satisfied” at the end of the evaluation and the other indicated she was “extremely satisfied”. The participant who did not complete the third week of the programme had reported being “satisfied” after both Week One and Week Two.

Table 5. Diary reports of satisfaction with the “Using Thinking Skills” self help programme.

Using Thinking Skills	Week One	Week Two	Week Three
Not at all satisfied			
Quite satisfied			√ (Week Four)
Satisfied	√√	√√	
Very satisfied	√	√	
Extremely satisfied			√

Participants allocated to each intervention group appeared broadly similar on baseline measures. Baseline RDQ scores ranged from 4/24 to 10/24 for the “Using Relaxation Skills” participants and from 5/24 to 8/24 for those allocated to “Using Thinking Skills”. The ranges of VAS scores were 30

mm to 54 mm (“Using Relaxation Skills”) and from 33 mm to 50 mm (“Using Thinking Skills”). All participants reported depressive symptoms, ranging from mild to moderately severe as measured by the PHQ-9, although none exceeded the cut off for severe depression. Baseline PHQ-9 scores ranged from 9 to 16.

Although it is not possible to draw any conclusions from the pre and post intervention measures data, Table 6 shows that one participant recorded worse pain after the “Using Relaxation Skills” self help programme but with no change in back pain specific functioning and an improvement in her mood as measured by the PHQ-9. The other two evaluators of this programme showed improved scores post intervention on all three measures.

Table 6. Pre intervention and post interventions scores for “Using Relaxation Skills” participants on the Roland & Morris Disability Questionnaire (RDQ), a visual analogue scale (VAS) of current pain severity and the Patient Health Questionnaire (PHQ-9) depression screening tool.

recruits	RDQ (pre)	RDQ (post)	VAS (pre)	VAS (post)	PHQ-9 (pre)	PHQ-9 (post)
no. 1	10	10	54 mm	62 mm	16	12
no. 2	4	3	35 mm	31 mm	13	8
no. 3	6	2	30 mm	11 mm	9	7

The two CD evaluators of the “Using Thinking Skills” programme for whom pre and post intervention data were available had improved post intervention scores on all three measures (Table 7).

Table 7. Pre intervention and post interventions scores for “Using Thinking Skills” participants on the Roland & Morris Disability Questionnaire (RDQ), a visual analogue scale (VAS) of current pain severity and the Patient Health Questionnaire (PHQ-9) depression screening tool. X denotes no data available.

recruits	RDQ (pre)	RDQ (post)	VAS (pre)	VAS (post)	PHQ-9 (pre)	PHQ-9 (post)
no. 1	5	4	44 mm	32 mm	11	8
no. 2	8	3	33 mm	31 mm	13	10
no. 3	8	X	50 mm	X	14	X

Finally, of the five participants for whom pre and post intervention data were available, two showed improvement on the SF-12v2 measure of role physical (three showed no change); three improved on the bodily pain scale (two had no change); two reported improved general health (three had no change); two scored higher on the vitality scale and one scored lower (two had no change); and all five had improved, post intervention scores for physical functioning, social functioning, role emotional and mental health.

5.6. Discussion of the pilot evaluation findings

The pilot evaluation of the new, self help audio CD on using progressive muscular relaxation to help manage early, non-specific low back pain suggests the programme is easy for GP patients to follow and understand and is highly acceptable to users. The three evaluators rated their satisfaction levels at the end of their three week programme at home as either “very” or “extremely” satisfied. No changes to the “Using Relaxation Skills” CD appeared to be warranted before proceeding with a trial of its effectiveness.

Two of the evaluators of the “Using Thinking Skills” programme volunteered they would have selected the relaxation, self help programme had they been given a choice, which may suggest that the latter programme might have wider appeal. This may be particularly true for people with lower educational attainment. The participant who completed the “Using Thinking Skills”

programme and who reported finding it “extremely satisfactory” was a university graduate. This self help programme does require a degree of ability to think in the abstract and to generalise in addition to a level of competence and confidence with reading and writing English, which may make it unappealing or simply too hard for some back pain patients. Using a self help method to learn independently to identify and challenge unhelpful and extreme thinking may be especially challenging. Regardless of any perceptions of the "thinking" course being intellectually harder, pilot evaluation participants described the idea of having time to themselves, and to spend it relaxing, made "Using Relaxation Skills" appealing.

In view of the feedback from the pilot evaluator who reported difficulty with the final part of the “Using Thinking Skills” programme, the researcher considered making changes to the worksheets for Week Three. After reviewing the materials, it was felt that making alterations might detract from their acceptability and usefulness to a sub set of the population to whom self help with “Using Thinking Skills” appealed without necessarily making them more attractive or easy to use for others who would prefer a relaxation programme. In the absence of evidence for which treatment is best suited to which patient with acute back pain, individual preference may be a reasonable guide to which intervention a patient should have (Hepple & Robertson, 2006). A future study of the effectiveness of the self help audio CDs could therefore include patient preference in the intervention arm in its design, rather than randomising participants to a particular intervention as was done in the pilot evaluation phase. This would attenuate any adverse influence on adherence and outcome from allocating a more intellectually demanding “Using Thinking Skills” programme to individuals for whom this was an unsuitable form of independent self help. Being able to select a self help programme would also accord with the expressed wishes of the pilot evaluators of the audio CDs; two of the six participants volunteered a personal preference for the relaxation programme and three indicated the same preference when they were asked by the researcher. Only one participant, who reported being very happy with using the “Using Thinking Skills” CD, responded when asked that she would also have been happy to try out the relaxation CD.

The participants' feedback may have been influenced by reporting back to the researcher whose voice was also on the intervention CDs. This was an unavoidable consequence of a project with a single researcher. The participants gave a range of feedback to the researcher, however, including one who volunteered the difficulties she had experienced with the final part of her self help programme. Participants also raised personal matters with the researcher, unrelated to the pilot evaluation of the CDs. It therefore appears, at least on the face of it, that they felt comfortable and were open in their interactions with the author of the CDs.

The secondary outcome measures in the CD evaluation - of back pain specific functioning, self reported pain, depressive symptoms and general health and well being - suggested the possibility that using self help audio CDs might have a positive impact on selective domains of health and well being, for example, on functioning and mood. It was noted that depressive symptoms were prominent in these participants, and depression may be an important factor in early back pain (Pincus et al., 2006). However, the PHQ-9 is primarily a screening tool and its use in the pilot evaluation and a future, CD effectiveness study was conceived as an assessment to avoid recruiting participants who were unsuitable for the research because of mental illness. While the SF-12v2 Health Survey will capture some data relevant to depressive symptoms pre and post intervention in a future trial of CD effectiveness (for example, it includes a measure of the construct of mental health), the trial aim is not to tease out the mechanisms underlying any benefits of using the audio CD programmes but simply to establish initially whether benefits can be demonstrated. Hence the PHQ-9 will not be administered other than at baseline in the next stage of the research; a plethora of measures not only increases the burden on research participants, it also increases the probability of reporting a positive, significant result by chance, that is, of a Type I error.

While observations based on such a small data set must be made with great caution, it was also noted that there may be the possibility of “ceiling effects” with this early back pain population. Some baseline scores were low on both the RDQ and the VAS, for instance, indicating relatively mild, baseline symptoms and suggesting that detecting significant improvements might be problematic. An effectiveness trial intends to show any statistically significant results after

comparing scores pre and post intervention, however, it is also important to indicate whether any statistically significant improvements that are found are of clinical significance. In this instance, it seems likely that using a 30% shift from baseline score will be the more useful, recommended method to detect clinically important changes as measured by the RDQ (Ostelo et al., 2008).

None of the participants taking part in the pilot evaluation of the audio CDs reported difficulties with understanding or completing any of the proposed trial measures. They completed their diaries at home and the other measures in the presence of the researcher, without any input from the researcher.

All of the recruits to the pilot evaluation study were female. Given the small numbers, this may be chance. Nearly half (16/34) of the original expressions of interest in finding out about the research came from men. However, it raises the possibility that there could be a sex difference in engagement with self help programmes for managing early back pain. If this appeared to be confirmed in a larger study sample for an effectiveness trial, the implications of any sex differences would require to be explored and discussed. For example, might a differential uptake of the intervention reflect women's greater engagement with health services generally, and might the female sex of the single researcher in this study also be an influencing factor?

Four potential participants cited back pain intensity as a reason for declining to join the pilot evaluation study. The requirement for participants to make journeys to meet the researcher to complete the study measures appeared to be a barrier to recruitment and potentially could bias any trial sample by excluding those with more severe, early back pain. A possible modification to the design of an effectiveness trial was therefore considered desirable, for example, having the outcome measures completed on-line or sent and returned by post. This might have potential disadvantages, such as losing face to face rapport between the researcher and the trial participants, which could influence adherence. On the other hand, there would be opportunities to communicate by telephone, post and email; all of the proposed outcome measures could be completed without the presence of the researcher; and minimal face to face contact with the

researcher would be closer to a “real life” scenario of receiving a self help audio CD that is taken home to be used unsupervised, with little, further input from a health professional. A pragmatic trial of intervention effectiveness should be distinguished from a double blind, randomised controlled trial of efficacy (Nathan et al., 2000). It is unlikely to be possible to “blind” trial participants to psychological interventions and the constraints of single handed, PhD research also render the ideal of blinding the researcher unattainable. Notwithstanding, pragmatic trials of treatment effectiveness are valuable research undertakings when the aim is to determine if an intervention is practicable and whether it has clinical and social benefits beyond a tightly controlled, clinical environment (Morley & Williams, 2002). In this instance, the overriding consideration was not to hamper the enrolment of potential, trial recruits. Recruitment is discussed further below.

Table 8. A comparison of features of efficacy trials, effectiveness trials and the trial being undertaken for this thesis.

	Efficacy trials	Effectiveness trials	Trial of self help, audio CDs for early, non-specific low back pain
Aims	To demonstrate measurable effects of a specific intervention in a highly controlled environment	To demonstrate if a treatment is feasible and has benefits in the real world	To demonstrate if self help audio CDs for early back pain are practicable and have benefits for users
Study design	Treatment group versus control group Random allocation of participants	Control group desirable but not always necessary Randomisation desirable but not always necessary	Random allocation to an intervention arm and a control arm Participant choice of one of two self help CDs within the intervention arm
Participant selection	Highly restrictive inclusion and exclusion criteria	Broader sampling, usually with less restrictive selection or no restrictions on who participates	Inclusion and exclusion criteria
Research protocols	Tightly defined protocols, manualised, with adherence checks	Clinicians not given special training to implement intervention	Standardised intervention on audio CD No face to face therapist heterogeneity
Outcomes	Theoretically important, predominantly clinical measures	Broader measures, such as disability and quality of life	Self reported pain, back pain specific functioning and general health and well being

From Table 8 it can be seen that the planned intervention trial is an effectiveness trial but shares some features of the “gold standard” of efficacy trials, the randomised, controlled trial. Sources of heterogeneity are controlled for to some extent by selection criteria for participants and by the standardised content and delivery of the intervention; there is a comparison control group, who do not receive any intervention; and participants will be randomly allocated to the control or intervention arm.

Recruitment to the pilot evaluation study was problematic. Despite the good will of a large GP practice with seven, full time partners, identification of potentially eligible recruits was slow and patchy, with some participating doctors failing to identify a single, possible patient for the CD evaluation study. A GP is working in a dynamic, time pressured environment in which the consultation with the patient is paramount; facilitating recruitment to external research during that consultation is unlikely to be a priority, notwithstanding helpful intentions and generally supportive attitudes towards primary care research. The recruitment rate suggested that a realistic expectation for recruitment to an effectiveness trial in primary care would not be more than approximately one participant a week, given a pool of approximately 11,000 primary care patients. This estimate was based on the results of an intensive and persistent approach to pursuing all possible leads generated by the surgery over a relatively short period of time, in which the existence of the research project was still fresh in people's minds. It might therefore tend towards overestimating enrolment rates over a longer recruitment period.

Problems with recruiting for primary care research have been reported elsewhere (Klaber Moffett, 1999; Bell-Syer & Klaber Moffett, 2000; Hay et al., 2005) and the difficulties encountered were similar to the difficulties documented in larger scale research studies in primary care settings. Likely problems with enrolling NHS GPs and their patients had been highlighted to the researcher by the NHS Lothian Research and Development Committee. Further, the prospect of improving the recruitment rate in a subsequent study by identifying multiple GP surgeries willing and able to participate seemed very slight given the recent withdrawal of support for small scale research projects by the Lothian and Borders Primary Care Research Network. An alternative strategy of having a very protracted recruitment period would not be feasible within the time constraints of a PhD study.

In addition to recognised difficulties with recruiting in primary care, there is the possibility that the recruitment difficulties experienced could be related to the nature of the intervention. As discussed in Chapter Two, there is little evidence available on which individuals choose to engage with which kinds of self help in health care and why. A self help programme for early, non-specific back pain

may have good, theoretical underpinnings yet lack popular appeal, especially where assumptions about good prognoses and biomedical attitudes persist among health professionals and the lay public (Koes et al., 2006; Bishop et al., 2008; Waddell et al., 2007). Arguably, this tentative explanation for slow recruitment is not strongly supported by the pilot evaluation study. About a third (six out of 17) of those who could be contacted and who were eligible agreed to trial the audio CD self help programmes, which suggests some level of interest in a self help approach from people with early back pain. Five of those enrolled had previous experience of episodes of back pain, which may perhaps have been a factor that encouraged these recurrent back pain sufferers to try a new, active approach to managing their back problems.

Ideally, the effectiveness of the new, back pain self help programmes would be investigated in a NHS primary care setting (Linton, 2002), however, the CD pilot evaluation study strongly indicated that, however desirable, this would be an impractical endeavour. It was therefore necessary to review plans for the proposed effectiveness trial with NHS patients and to consider ways of overcoming difficulties with recruiting into such a trial. For instance, a more realistic recruitment rate might be achieved by moving the early back pain research out of a primary care setting. A significant proportion of the population, estimated at 80%, who have low back pain symptoms may not consult a GP (for example, Papageorgiou & Rigby, 1991; Waddell, 2004). An initial trial of the effectiveness of self help audio CDs for low back pain might be carried out in a more timely fashion by widening the research net to include people with early back pain who met the eligibility criteria but who were not identified via a GP consultation. The self help materials had been designed and produced with a primary care population specifically in mind, nonetheless, the audio CD programmes and the proposed outcome measures were also suitable for use in the general population. The ethical concern raised by a change to the study population was that potential recruits would not necessarily have a GP diagnosis of non-specific low back pain. It was felt care would need to be taken to try to ensure that only suitable recruits – those whose back pain symptoms did not indicate a need for medical supervision - were enrolled. This could be achieved by a more detailed, screening interview when the researcher checked the eligibility of those potential participants who reported they had not previously consulted a doctor about their back pain problems.

The researcher then considered how to reach members of the public who were experiencing an episode of early back pain. It was decided to approach a large, local, financial company to ask it to become involved in the early back pain intervention trial, as well, perhaps, as inviting members of the general public to participate through posters and newspaper notices. The exploratory trial of the effectiveness of self help, audio CDs for early, non-specific low back pain that was undertaken in the community is reported in Chapter Six.

5.7. Summary of Chapter Five

- Overall, both new, self help audio CDs for early, non-specific back pain could be acceptable to users and the “Using Relaxation Skills” programme was particularly well received
- Participant feedback indicated a wish to select a self help programme based on personal preference for either “Using Relaxation Skills” or “Using Thinking Skills”
- Trial measures could be sent and returned by post or electronic mail, removing the need for participants to travel to study appointments; face to face appointments may be a barrier to recruitment, especially among those with more painful back symptoms
- Recruitment into the pilot evaluation in primary care was slow and labour intensive, consistent with previously reported difficulties with undertaking research in primary care in the U.K.
- There is a pragmatic requirement to broaden the potential participation base for a subsequent, exploratory trial of CD effectiveness by recruiting outside the NHS
- The self help materials and proposed outcome measures are appropriate for use in the community

6. Chapter Six. Pragmatic randomised controlled trial of CD effectiveness.

6.1. Introduction

This chapter reports a pragmatic, randomised controlled trial of the effectiveness of self help, audio CDs for early, non-specific low back pain in the community.

The literature reviewed in Chapters One to Four demonstrated the very limited research into improving early treatment for acute episodes of non-specific low back pain, despite a prognosis for a substantial proportion of “acute” back pain sufferers of fluctuating, persistent and recurrent symptoms. The available evidence on enhancing self management to improve outcomes in early, non-specific low back pain suggested that self help materials for home use, which were based on CBT, including learning relaxation skills, had the potential to address prognostic psychological and behavioural variables before they became stable and perhaps maladaptive. A pilot evaluation of two, new audio CDs for enhancing self management of early back pain, “Using Relaxation Skills” and “Using Thinking Skills”, showed that both programmes could be acceptable to adults consulting their GP with low back pain (Chapter Five). The three week, self help, audio programmes for use at home provide information and reassurance about non-specific low back pain and encourage early, active self management, either by focussing on learning progressive muscular relaxation skills or by learning “thinking skills”, such as problem solving and identifying unhelpful thinking. Both CDs' contents are components of CBT programmes for pain management. The decision to trial the effectiveness of the CD programmes in the community was a pragmatic one, based on the experience of difficulties with recruiting NHS primary care doctors and their patients into independent, smaller scale research.

The aim of this trial is to investigate whether adults in the community with a current episode of early, non-specific low back pain benefit from using a three week, self help, audio CD programme at home.

The trial reported here is a pragmatic, randomised controlled trial. As such, it is grounded in an epistemological position of there being some objective reality, independent of subjective interpretations and amenable to testing and measurement. A quantitative methodology has historical links with positivism, empiricism and the development of the “scientific method”. A belief that the scientific method is the most appropriate way to establish valid and reliable, health related evidence underpins a contemporary drive to define and implement Evidence Based Medicine (EBM) in the NHS. The double blind, prospective randomised controlled trial (RCT) is considered the “gold standard”; the value to EBM of available research evidence is ranked, with strong evidence from systematic reviews of RCTs heading the hierarchy, followed by strong evidence from at least one, well designed and appropriately large RCT (www.evidence-based-medicine.co.uk).

An ethical RCT assumes equipoise – that a new treatment under investigation will be at least as good as the standard treatment with which it is compared – and researchers attempt to control for confounding factors to reduce bias, for example, through rigorous participant selection and randomisation procedures. However, criticisms of the dominant position of the RCT in a hierarchy of evidence include “publication bias” (trials reporting significant results are more likely to be published) and the difficulties of translating findings from tightly controlled RCTs that report group means into everyday practice with individual patients (Simon, 2006). While accepting a need for basic science research and an important role in health research for “gold standard” RCTs, it can be argued that a wider approach to NHS EBM is desirable. An argument for valuing evidence beyond RCT evidence may be particularly relevant where chronic disease management and life style interventions are concerned (Lean et al., 2008).

According to Lean et al. (2008), health practitioners, policy makers, patients and the public need to have access to health related evidence that is derived from various methodologies and methods. They state:

“A simplistic view presupposes that after treatments are rigorously evaluated, results are incorporated into clinical guidelines within best practice criteria, which, in turn, inform policies.

However, the process that leads to effective, sustainable solutions to health problems is in fact non-linear, with different forms of evidence needed at different stages by different parties.” (p. 705)

The pragmatic, randomised controlled trial reported in this thesis may be compared to a “gold standard” RCT. It differs in important respects, specifically, it aims to demonstrate whether implementing an audio CD intervention for the public is feasible and can show benefits in the real world. This distinguishes it from RCT research with patients in a tightly controlled, clinical environment. Further, there are broader criteria for enrolment of members of the public than would be the case with highly restrictive, patient selection criteria for a “gold standard” RCT. Finally, the outcome measures encompass quality of life and self reported disability measures whereas a “gold standard” RCT would typically focus on measures of specific, clinical outcomes.

“Pragmatic” indicates that the thesis trial concerns an intervention made available to members of the general public, who continue to conduct their everyday lives in their particular socio-economic and cultural environments. Nonetheless, the thesis trial also shares some features that are associated with “gold standard” RCTs. It is controlled to some extent, through having some eligibility criteria to select trial participants, through the standardised content and delivery of the audio CD intervention and through having a control group of participants, who receive no audio CD, with whom to compare outcomes. It is also randomised, with participants allocated to a control or an intervention group by applying approved (computer generated) randomisation procedures.

This chapter describes the trial participants, the study objectives and the hypotheses being tested. It gives details of the procedures followed to conduct the trial and describes the statistical methods employed to compare the intervention group and a control group. The intervention materials and the outcome measures are described fully in the preceding chapter (Chapter Five) and are presented more briefly in the Methods section here. The study results are reported. The findings are discussed further in Chapter Eight.

Ethical permission for this trial was obtained from Queen Margaret University's Research Ethics Committee.

6.2. Abstract

A pragmatic, randomised controlled trial of new, self help, audio CDs for early, non-specific low back pain was carried out in the community. The primary objective was to demonstrate whether a self help programme, to enhance active, early self management for non-specific low back pain and designed to be used independently at home, showed benefits with respect to back pain specific functioning as measured by the Roland and Morris Disability Questionnaire (RDQ). Forty four members of the public with an episode of back pain that had persisted between two and nine weeks were randomised to an intervention or a control group, which received no intervention. Back pain specific functioning, self reported pain intensity and general health and well being in physical and mental domains were assessed at baseline and at one month and six months. Data analysis conducted using a mixed between-within subjects analysis of variance demonstrated significant improvement across all measures over time for all participants. Compared to controls, those using a self help, audio CD showed significantly improved scores on the RDQ over time [$F = 6.673$, $p = .013$], although the magnitude of the mean group differences was small (partial eta squared = .137). It is concluded that a three week, home based, self help programme delivered by audio CD has the potential to improve functional outcomes in the short to medium term in early, non-specific low back pain.

6.3. Methods

The Method section describes in detail: the recruitment strategies for the trial; the participants and how they were randomised; the objectives and hypotheses of the study; the intervention materials, outcome measures and statistical analyses that were employed; and the procedures that were followed.

6.3.1. Recruitment

Entry into a prize draw was offered as an incentive to enrol in the study. All eligible participants who completed the study were entered into a draw with a winning prize of £100 being awarded at the close of the research in July 2007. It was hoped the prize draw money would encourage enrolment

and the completion of follow up measures while keeping the costs of providing participant incentives manageable.

There were three phases to recruitment, which took place in 2006. The first phase entailed discussing the CD effectiveness trial with the Occupational Health Manager of a large, Scottish financial institution. This organisation agreed to support recruitment to the trial by circulating information about the research to staff at its local head office. It was felt important to convey to staff that the back pain research was being carried out with the approval of the company's Occupational Health Department but independently of it; the company would have no access to information on which staff members chose to participate nor to any information gathered by the researcher as a result of their individual participation. Possible ways of giving out trial information to the staff were discussed, such as arranging an on-site presentation by the researcher and placing posters inside the office building. Management felt the most appropriate method was only to circulate information on the organisation's Intranet, which can be accessed by all staff working in the company's office. A notice about the research was placed on the home page of the Intranet, with a link to access Word documents that gave full details of the research project and the researcher's contact details. Eighteen eligible staff members from this organisation were enrolled into the study.

A second, large employer was approached by the researcher, however, after an initial meeting to discuss the research, this financial organisation declined to inform its staff about recruitment into the trial. The organisation gave its reason for declining, which was that its Occupational Health Department was shortly to embark on its own research project that would involve staff members with back pain; having two, back pain related research projects under way simultaneously within the organisation was felt to be inappropriate.

In the second phase of recruitment, in an effort to access a wider pool of potential participants and to complete the CD effectiveness trial recruitment in a timely manner, the researcher made an A4, colour poster to advertise the back pain research to members of the general public (Appendix 9). Local authority public libraries and leisure centres and some local shops were approached with a

request to put the A4 poster on display. Few shops agreed to do this – few had notice boards or an equivalent space for displaying such materials - however, several libraries and leisure centres had public notice boards and the researcher was given permission to display the back pain study posters on these. Simultaneously, a notice about the research was placed in two publications, a free paper and a local evening paper. Each notice appeared on three occasions over three weeks. Eleven eligible members of the public were recruited via the posters and nine via the classified advertisements placed in newspapers.

In the third and final phase of recruitment, a moderator message requesting recruits for the research was circulated to all staff members and students at the researcher's institution. Responses to this email produced a further six, eligible participants.

Potential recruits contacted the researcher by email and/or by telephone, using the contact details given on the Intranet, posters, newspaper adverts and moderator's email. All potential recruits were sent full details of the study and a consent form as email attachments or by post. In addition, the researcher spoke to potential recruits on the telephone if they did not report having a current or recent doctor's diagnosis of non-specific low back pain. Additional enquiries about their back pain symptoms and general health aimed to confirm their eligibility for a trial concerned with non-specific back pain. Signed consent forms were returned by post. Copies of the information sheet and consent form are available in Appendix 6.

Time constraints for completing the thesis meant recruitment into the study had to be closed at the end of 2006, by which time the combined recruitment strategies had resulted in a total of 44 enrolments. Many enquiries generated by the various strategies were from potential participants who proved to be ineligible (see Figure 1). It was noted this was particularly the case for enquiries generated by the posters and newspaper advertisements, perhaps because these methods of publicising the research allow less initial information to be imparted.

6.3.2. Participants

Forty four, eligible participants with an episode of non-specific low back that had persisted between two and nine weeks were enrolled into the trial after providing the researcher with signed, written consent forms.

The trial inclusion criteria were:

- aged between 20 and 65 years inclusive
- written, informed consent
- access to a CD player at home and a telephone
- acute, non-specific low back pain that has persisted for at least two weeks, either new pain or a recurrent acute episode
- able to read and write English

The exclusion criteria were:

- painful chronic illness; current diagnosis of clinical depression or severe depressive symptoms on screening; dementia
- specific low back pain diagnosis
- non-specific back pain episode of less than two weeks' or more than nine weeks' duration

- previous participation in a back pain management programme, for example, physiotherapy with a CBT component
- current enrolment in other medical or psychological research

Data were collected in 2006 and 2007. The RDQ, SF-12v2, VAS and PHQ-9 were emailed or posted to participants. Stamped, addressed envelopes were provided for participants not using email (n=4) to return their study measures. After the researcher had received the completed baseline measures by email or post, participants were informed of their study group allocation. Group allocation was in accordance with computer generated lists of random numbers (see Section 6.3.7.). Those allocated to the intervention arm were posted the self help programme package of their choosing. Four to five weeks later, the RDQ, SF-12v2 and VAS measures were sent out electronically or by post, with a reminder to participants in the intervention arm also to return their self help programme diaries. The RDQ, SF-12v2 and VAS measures were sent by email or post for a third time 26 weeks later (plus or minus one week). At each data collection time point, the researcher contacted any participant whose study measures had not been returned within one week for those using email and within two weeks for those using the postal service.

One participant responded to a second, email reminder to return his baseline measures with an email notifying his withdrawal from the study, without giving a reason. This recruit provided no data. One participant in the intervention arm ("Using Relaxation Skills") did not respond to two email reminders for the return of her post intervention measures at one month and was therefore assumed to have withdrawn from the study; it is not known whether or not she used the self help programme sent out to her. One participant in the control group provided data at baseline and at one month follow up but did not respond to two email reminders requesting the return of her study measures at six month follow up. The other 41 participants provided full data at all three time points.

6.3.3. Intervention

Participants in the intervention group chose one of two, self help audio CDs, giving information and reassurance about non-specific low back pain and either training in progressive muscular relaxation or training in CBT based, “thinking” skills for pain management. Each programme requires listening to one audio session at least once at the start of each of the three weeks of the programme. Both audio CDs begin by giving exactly the same factual information on the condition of acute, non-specific low back pain, with reassurance in the absence of serious spine disease that “hurting does not equal harming” and advice on pain control, and both programmes take the same amount of time (approximately 25 minutes a day for three weeks) to complete at home. Daily skills practice throughout each programme is strongly recommended. Worksheets are provided to accompany the “Using Thinking Skills” programme (Appendix 3).

6.3.4. Objectives and hypotheses

The primary objective is to compare back pain specific functioning in daily living, pre and post intervention, in adults using a self help, audio CD for early, non-specific low back pain and in similar adults who have no intervention. Secondary objectives are to compare the audio CD intervention group and controls on measures of general health and well being and of self reported pain intensity, pre and post intervention. It is predicted that both groups will show improvements in the study outcome measures between baseline and six month follow up and that self reported pain intensity will not differ significantly between the groups. In addition, it is predicted that the intervention group will demonstrate significantly improved outcomes on measures of back pain specific functioning and general health and well being over time compared to the control group. The hypotheses are:

- Null hypothesis 1: There will be no significant, between group differences in observed changes to RDQ scores over time

- Hypothesis 1: Compared to controls, participants in the self help, audio CD intervention group will show significant improvements in back pain specific functioning as measured by the RDQ
- Null hypothesis 2: There will be no significant, between group differences in observed changes to SFv12 summary scores for physical and mental health and well being over time
- Hypothesis 2: Compared to controls, participants in the self help, audio CD intervention group will show significant improvements in physical and mental health and well being as measured by the SFv12 summary scales

6.3.5. Outcome measures

The primary outcome measure is the Roland & Morris Disability Questionnaire (RDQ). Secondary outcome measures are the Mental Composite Scale (MCS) and the Physical Composite Scale (PCS) of the SF-12v2 Health Survey; and self reported pain intensity measured by a Visual Analogue Scale (VAS). The Patient Health Questionnaire (PHQ-9) is administered at baseline to screen for severe depressive symptoms.

In addition, participants allocated to the intervention group were asked keep a diary to record their use of the self help, audio CD and to rate their satisfaction with it (Appendix 4).

All these measures are described fully in the preceding chapter (Chapter Five) and will be outlined again more briefly below. The internal reliability of the scales in this study are reported. The exceptions are the summary scales for mental and physical health and well being that are derived from the eight health domain scores in the SF-12v2 Health Survey. Due to the nature of this scale, which measures distinct health domains and uses few questions per domain, advanced statistical techniques are required to calculate reliability estimates (Ware et al., 2005). The summary scales of the SF-12v2 are described below.

Intervention effectiveness is measured by the RDQ (Roland & Morris, 1983; Bombardier, 2000), a reliable, validated, self-completed, 24 item assessment to measure back pain specific, functional limitations in daily living. The questions cover a range of items, including mobility, self care, appetite, irritability and sleeping. The RDQ response is dichotomous; respondents indicate whether or not statements are true for them in the last 24 hours. Positive responses are summed to give a total score, with a higher score indicating greater functional disability. A change of five points or greater on the RDQ or a 30 per cent change from the baseline score are considered to be of clinical significance (Ostelo et al., 2008). Consistent with previously reported, good internal reliability, in this study the Cronbach alpha co-efficient was 0.88.

Examples of items from the RDQ are: I walk more slowly than usual because of my back; Because of my back, I try to get other people to do things for me; My appetite is not very good because of my back pain; I sleep less well because of my back; Because of my back pain, I get dressed with help from someone else. The RDQ is freely available on the Internet (<http://www.rmdq.org/>). See Appendix 7.

Generic health and well being is assessed by the validated SF-12v2 Health Survey (Ware & Dewey, 2002). It was developed as a shorter, quicker-to-complete alternative to the SF-36v2 Health Survey and measures the same eight health constructs. The constructs are: physical functioning; role physical; bodily pain; general health; vitality; social functioning; role emotional; and mental health. Items have five response choices, apart from two questions for which there are three response choices (for the physical functioning domain). Four items are reverse scored. Summed raw scores in the eight domains are transformed to convert the lowest possible score to zero and the highest possible score to 100.

The summary scales for mental (MCS) and physical (PCS) health and well being are computed from the eight health domain scales in three steps. Firstly, the eight domain scales are standardised using means and standard deviations (SD) for the 1998 general U.S.A. population. Secondly, the eight scales are aggregated using weights from the 1990 U.S.A. general population.

Thirdly, the aggregated measures are standardised using a linear t-score transformation to give a mean of 50 and a standard deviation (SD) of 10 in the 1998 general U.S.A. population. There are three advantages of using the MCS and PCS summary scales: they reduce the number of group comparisons in the analysis of the data, and thereby reduce the probability of finding a significant difference by chance; they achieve greater statistical power in detecting differences in mental and physical health than any one of the eight, domain scales from which they are derived; and standardised summary scales can be directly compared across different studies and in different countries. Using the standard, U.S.A. derived scoring algorithms is reported to be appropriate in the U.K., based on evidence from evaluations using large, general population samples (Gandek et al., 1998). Higher MCS and PCS summary scales represent better health and well being. The standard form SF-12v2 uses a time frame of the past four weeks.

Reported reliability estimates for the summary scales are 0.89 and 0.86 for the PCS and the MCS respectively. For a description of the statistical techniques employed to estimate reliability coefficients for the PCS and the MCS, see Ware et al. (2005).

Examples of items from the SF-12v2 are: During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?: not at all, a little bit, moderately, quite a bit, extremely; During the past four weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?: all of the time, most of the time, some of the time, a little of the time, none of the time. The SF-12v2 is available for a fee under licence from QualityMetric Incorporated (www.QualityMetric.com).

Pain severity is assessed using a 100mm visual analogue scale (VAS). At either end of the horizontal line is a small, vertical mark and a verbal description ("not at all painful" at the left extremity and "extremely painful" at the right). Participants are asked to mark the line at the point that best represents the current severity of their back pain. The score is the distance measured from the left hand of the VAS ("not at all painful") to the participant's mark. The VAS is reliable and

valid (Jensen & Karoly, 2000). VAS measurements correlate highly with other brief, self rated pain measures with better responsiveness to change than scales with more limited response options (Downie et al., 1978). It has the advantage of ratio scale properties for statistical analysis (Price et al., 1994). A difference of 30 mm between line marks on different occasions is considered to represent a clinically significant change in acute low back pain (Mannion et al., 2007), as would a 30% shift from baseline score (Ostelo et al., 2008).

The Patient Health Questionnaire (PHQ-9) is a self administered screening tool for depression (Kroenke et al., 2001). Its nine items assess anhedonia, mood, sleep, fatigue, appetite, concentration and self-harm ideation in the past two weeks. Each item has four response choices from “0” (not at all) to “3” (nearly every day). All the scores are summed to give a total score between 0-27, with a higher score indicating greater depression. Validity has been assessed against an independent, structured mental health professional interview, which showed a PHQ-9 score ≥ 10 had a sensitivity of 88% and a specificity of 88% for depression. A cut-off point of 20 is suggested as positive for severe depression. Potential research participants with screening scores indicating severe depression are ineligible for the study. In the current study, the Cronbach alpha coefficient was 0.95.

Example items from the PHQ-9 are: Over the last two weeks, how often have you been bothered by any of the following problems? Little interest or pleasure in doing things; Trouble falling or staying asleep, or sleeping too much; Feeling tired or having little energy; Trouble concentrating on things, such as reading the newspaper or watching television; Thoughts that you would be better off dead, or of hurting yourself in some way. The PHQ-9 is freely available on the Internet (for example, at <http://www.patient.co.U.K./showdoc/40025272/>). See Appendix 8.

Each intervention CD was accompanied by a daily diary to monitor programme use and satisfaction. The diary provided daily use and weekly satisfaction rating scales and a page for free text if participants wished to write their own comments (Appendix 4).

6.3.6. Sample size

Although researchers are generally interested in drawing conclusions about their hypotheses, statistical analyses of study results provide conclusions about the null hypotheses. Hypothesis testing gives the probability of finding the result that was observed if the null hypothesis were true, or the probability of a Type 1 error. If the probability of a Type 1 error is less than a specified value (alpha), the null hypothesis is rejected (and the researcher's hypothesis is supported). Alpha is commonly set at .05, although it is set at this level by convention. Beta is the probability of a Type 2 error, that is, of accepting a false null hypothesis. The power of a study is defined as the probability of correctly rejecting the null hypothesis and is given by $1 - \beta$. Again by convention, a power of 80% is normally considered acceptable (Cohen, 1988; Kraemer & Thiemann, 1987). The sample size needed to detect a true difference between groups, depending on the magnitude of the difference, can be calculated using alpha, the study power and the estimated effect size based on, for example, clinical knowledge, previous research findings or conventions for small, medium or large effect sizes for different types of statistical tests (Cohen, 1988).

For this study, an a priori sample size calculation was carried out using G*Power software (Faul et al., 2007). The trial was designed to be exploratory, investigating the effectiveness of new intervention materials for which there are no previously published data to indicate an expected effect size. Given the heterogeneity of non-specific low back pain and the likelihood of symptom reduction over time in acute episodes, it was assumed that the magnitude of any observed differences between the CD intervention group and the control group would be likely to be small, therefore a small effect size for F tests was selected (Cohen, 1988). Detecting small effect sizes requires greater numbers of study participants. An ANOVA repeated measures within-between interaction was selected from the G*Power drop down menu and input parameters of effect size f (0.15); alpha (.05); power (.80); two groups; and three repetitions – at baseline, follow up one and follow up two - were entered. Default settings were accepted for correlations among repeated measures and nonsphericity correction (0.5 and 1 respectively) as these were not known for this study in advance. The calculated, required sample size was 74 (37 in the intervention group and 37 controls).

The sample size of 44 achieved in the time available for recruitment and follow up in the present study fell below this target.

6.3.7. Randomisation

Enrolled participants were randomised to the intervention group or the control group using computer generated sequences of random numbers in successive blocks of 10 (<http://graphpad.com/quickcalcs/randomize1.cfm>). The researcher generated the allocation sequence, enrolled the participants and assigned participants to their groups. Neither the researcher nor the participants were blinded to the group allocations.

Those randomised to the intervention group were invited to choose either the “Using Thinking Skills” self help programme or the “Using Relaxation Skills” programme based on personal preference. Six participants (three women and three men) selected “Using Thinking Skills” and 17 participants (12 women and five men) chose “Using Relaxation Skills”. For the purposes of analysis, participants using either of the two audio CD programmes were combined into one intervention group.

6.3.8. Statistical methods

Outcome measure data were analysed in a mixed between-within subjects analysis of variance, which is also known as a split-plot ANOVA (SPANOVA). The SPANOVA combines a between group comparison for one independent variable - in this instance, the treatment variable (intervention group, control group) - with a repeated measures design for a second, independent variable - for this trial, time (baseline, follow up one and follow up two). The within subject variation is a description of how much change is observed in the scores for each individual. The between subject variation describes how much change is observed in the scores between participants. Analysis of variance designs compare the variability of scores within each study group to the variability of scores between the different study groups to calculate an F ratio, where larger F ratios indicate

there is greater between group variance (which is assumed to be caused by an independent variable).

As data for this trial were collected from the same measures from each participant at three time points, statistical analyses that assume that the data are independent of one another are unsuitable. Further, performing multiple comparisons, such as t-tests, at each data time point would increase the probability of observing a significant, between group difference by chance. An additional advantage of the repeated measures design is that it has more power to detect differences between groups based on fewer observations. The researcher used SPSS software (version 15.0) to conduct the data analyses.

When there are observations that have missing values, as was the case in this study - missing values for one participant at time point 1 (baseline), missing values for two participants at time point 2 and missing values for three participants at time point 3 – these may be filled by the mean score for that variable in that participant's group. A disadvantage of substituting the group mean score in this way is that it could influence the reported standard deviations, which reflect the ranges of scores observed. Alternatively, the observations that have missing values can be removed from the analysis altogether. This has the disadvantage of depleting the data set. For the purposes of this study, which achieved a sample size below its target, it was considered preferable to retain all participants in the data set for analysis. Therefore mean group scores were substituted for those variables where there were missing observations.

Exploratory data analysis confirmed an extreme outlier in the data set. This participant had been enrolled into the study on the basis of his meeting the eligibility criteria, however, his PHQ-9 score at baseline screening for depressive symptoms, 19, was the highest of the recruits; the cut off PHQ-9 score for inclusion in the trial was 19, with a score of 20 or more being considered indicative of severe depressive symptoms. He was randomised into the intervention group and chose “Using Thinking Skills”, which he later reported had “helped” him. However, this participant went on to develop a series of medical and psychological problems, which were discussed with the

researcher by telephone after he had returned his outcome measures at time point 3. The participant described having had diagnoses subsequent to his enrolment of gout, gum disease, digestive problems and clinical depression, combined with social problems related to his housing. The participant was unemployed. It was established during the telephone conversation that he was currently receiving medical care.

Many parametric statistical techniques are highly sensitive to extreme outliers (Pallant, 2001). Some statisticians recommend cleaning all extreme outliers from the database to prevent them from distorting the statistics, although this may be a controversial solution to the problem. There is a strong argument for their retention when they have been enrolled in accordance with the trial inclusion criteria and therefore represent a member of the population of interest for the intervention research. Indeed, there is the possibility that, given a larger sample size, there might have been other participants exhibiting similar scores. Other statisticians recommend adjusting the extreme, observed values, for example, by substituting such scores with the mean score for that variable in the outlier's group. The latter has the advantage of not excluding eligible participants from the data analysis (Pallant, 2001; Tabachnick & Fidell, 1996). To allow parametric statistical tests to be run on the data set here and to avoid seriously distorting the statistics and depleting a relatively small sample, it was judged preferable in this study to keep the extreme outlier in the analysis but with substituted mean scores for the intervention group replacing his extreme scores. Two further, less extreme outliers were observed in the intervention arm. Inspection of the 5% Trimmed Means indicated that these remained close to the original means and it was therefore decided to retain these outliers in the data set, with no adjustments to their observed scores.

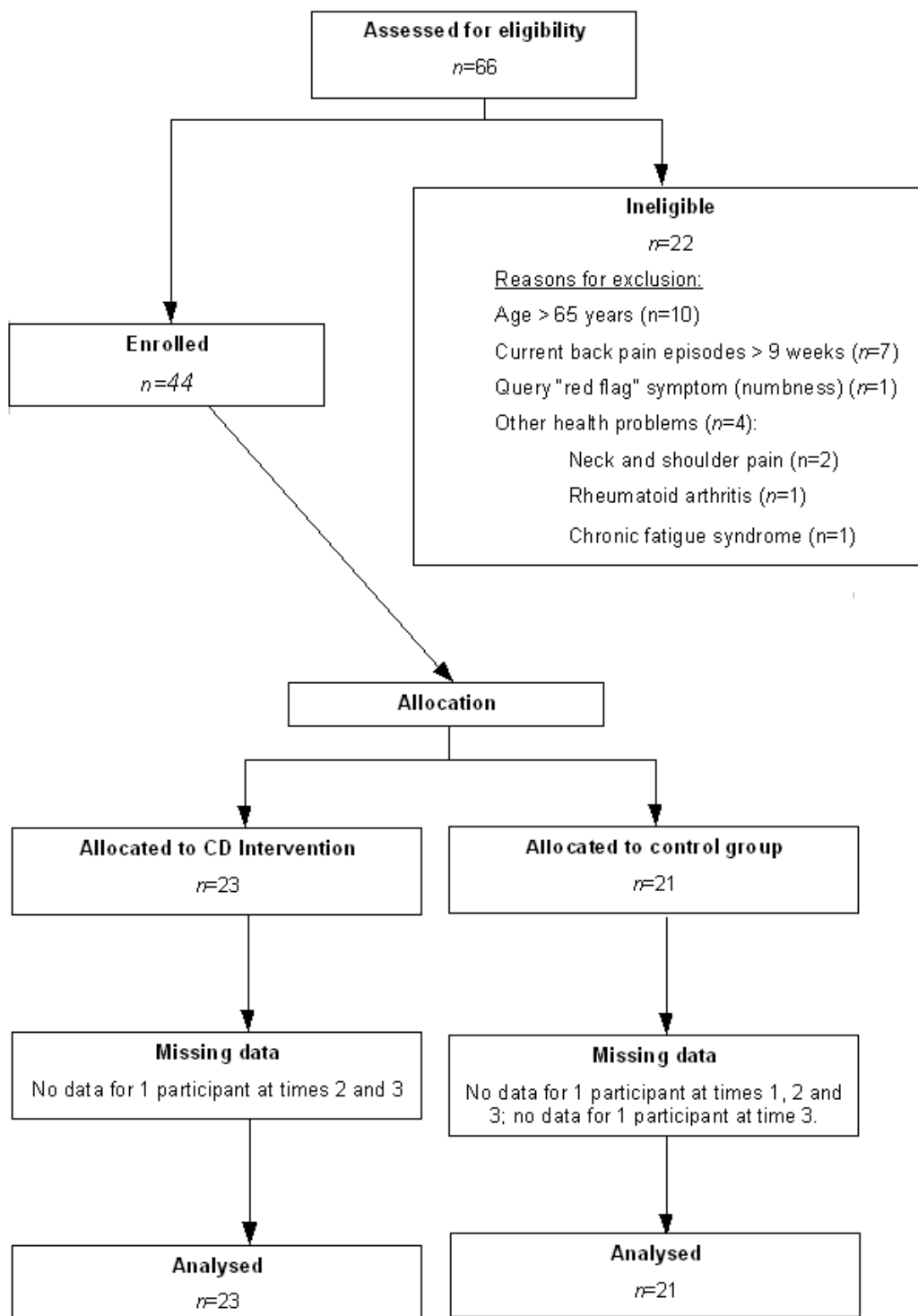
6.4. Results

6.4.1. Participant flow

A flow chart (Figure 1) is presented on the following page. It gives a graphic representation of the information supplied above. All 23 participants in the intervention arm and all 21 participants in the control arm were included in the statistical analyses, following substitution of group mean scores

for missing observations (and for the extreme outlier). The descriptive, exploratory statistics were performed on the original, unadjusted data set. Accordingly, tables presented in the descriptive statistics that follow show 20 participants in the control arm, rather than 21: one participant withdrew after enrolment.

Figure 1: Participant flow



6.4.2. Baseline characteristics and descriptive statistics

The majority of participants (37/44) were experiencing a recurrent episode of low back pain. Only three participants had consulted the GP for the current episode of back pain although many (28/37)

with recurrent pain reported having done so on a previous occasion. No participant was currently having or waiting to have NHS physiotherapy and none was using a privately funded therapist for back pain. The vast majority (42/44) reported taking oral analgesics to control painful symptoms. Most recruits were in employment (41/44) and nearly half of these had taken some time off work due to back pain symptoms in the month prior to enrolment. Absenteeism among the 19 participants who reported lost work days in the previous month ranged from one day to five days, with a mode of two days.

Table 9.

Baseline characteristics of the sample allocated to the self help CD intervention.

Variable	Number	Mean (SD)or %
Age in years	23	44 (12.06)
Sex female male	23	69.6% 30.4%
Status single married/partner divorced	23	26.1% 56.5% 17.4%
Educational attainment school leaver college diploma university degree	23	34.8% 21.7% 43.5%

As the participants were randomly allocated to the intervention group or to the control group, it may be assumed that any differences in baseline characteristics between the two groups have arisen by chance (Peacock & Kerry, 2007). It can be seen from Tables 9 and 10 that the two groups were broadly similar for baseline characteristics.

Table 10.

Baseline characteristics of the sample allocated to the control group.

Variable	Number	Mean (SD) or %
Age in years	20	46 (9.99)
Sex	21	
female		57.1%
male		42.9%
Status	20	
single		28.6%
married/partner		47.6%
divorced		23.8%
Educational attainment	20	
school leaver		23.8%
college diploma		33.3%
university degree		42.9%

All the participants who completed a self help audio CD programme for the study rated using their programme as: satisfactory (n=2); very satisfactory (n=14); or extremely satisfactory (n= 6).

The mean score for back pain specific functioning as measured by the RDQ at baseline was $M=6.13$ ($SD=3.28$) for the intervention group and $M=6$ ($SD=2.53$) for the control group, indicating that in terms of back pain specific, functional disability in daily living, the groups were comparable and neither group mean suggests significant disability due to back pain symptoms (see Tables 11 and 12).

Table 11.

Dependent variable baseline measures for the intervention group.

Intervention group	Number	Mean	SD
PHQ-9	23	8.83	3.737
VAS 1	23	48.04	20.956
PCS 1	23	42.96	5.076
MCS 1	23	39.61	6.437
RDQ 1	23	6.13	3.279

Table 12.

Dependent variable baseline measures for the control group.

Control group	Number	Mean	SD
PHQ-9	20	7.85	2.661
VAS 1	20	50.25	19.870
PCS 1	20	43.95	5.853
MCS 1	20	40.45	6.684
RDQ 1	20	6.00	2.534

The data were re-checked to ensure no mistakes had been made in entering scores when box plots revealed three outliers, one extreme, on baseline measures of pain intensity and depressive symptoms. Following adjustment to the extreme outlier's observed scores (by substitution with the intervention group mean for that variable), the data were checked for normality and were found not to violate assumptions underlying parametric tests.

The predictive ability of the baseline variables was explored, with the main outcome measure, the RDQ, as the dependent variable in a standard multiple regression analysis. This was to assess how much variance in baseline RDQ scores could be explained by baseline scores on the secondary outcome measures and by the participants' mood at baseline as measured by the

PHQ-9. This model, which includes the variables of PHQ-9, VAS, PCS and MCS, explains 67.3% (adjusted R Square 0.673) of the variance in back pain specific functional disability. Both mood and pain intensity make significant and unique contributions to explaining the dependent variable, with mood making the stronger contribution (PHQ-9 standardised Beta coefficient 0.566; $p < 0.5$; VAS standardised Beta coefficient 0.487; $p < 0.5$).

6.4.3. Data analysis

The results of the analysis of the data set using a mixed between-within subjects analysis of variance are now presented, reporting the main effects for each independent variable (treatment and time) and associated effect sizes and interaction effects.

A mixed between-within groups analysis of variance was conducted to compare scores on back pain specific functioning as measured by the RDQ at time 1 (baseline), at time 2 (one month follow up) and at time 3 (six month follow up) and the impact of study group (intervention versus controls). The means and standard deviations are presented in Table 13.

There was a significant effect for time (Wilk's Lambda=3.44, $F(2, 41)=39.12$, $p < .05$, partial eta squared=.656). RDQ scores reduced – therefore improved - across the three, different time periods. This improvement over time is illustrated in Figure 2. The interaction effect, indicating whether the changes in scores over time were the same for the two different study groups, also reached significance ($p=.001$), however the effect size was small (partial eta squared=.299).

There was a statistically significant main effect for study group [$F=6.673$, $p=.013$]. The effect size was small (partial eta squared=.137). This result supports the hypothesis that there would be a significant improvement in RDQ scores over time in the intervention group compared to the control group, although the magnitude of the effect is small. It is concluded that Null Hypothesis 1 should be rejected.

From Figure 2, it can be seen there is a greater between group difference at time 2. To ascertain whether this is where the significant, between group difference lies or whether a significant difference was also demonstrated at six months requires post hoc analysis.

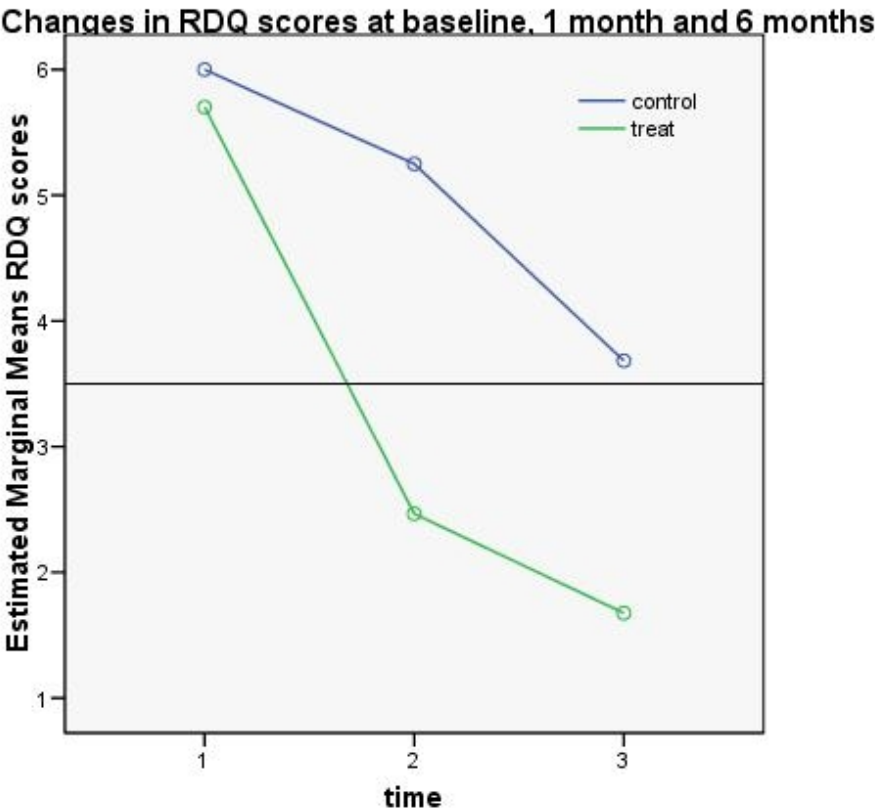
In terms of clinical significance (Ostelo et al., 2008), the intervention group demonstrates clinically significant improvements in RDQ scores at each study interval, that is, between baseline and one month, between one month and six months and, overall, between baseline and the six month follow up. For the control group, a clinically significant improvement in RDQ scores is seen in the overall reduction in scores between baseline and six months only.

Table 13.

RDQ Descriptive statistics for RDQ scores for time 1, time 2 and time 3.

	Group	Mean	SD	N
RDQ 1	Control	6.00	2.47	21
	Treat	5.70	2.47	23
	Total	5.84	2.45	44
RDQ 2	Control	5.25	3.16	21
	Treat	2.47	1.85	23
	Total	3.79	2.89	44
RDQ 3	Control	3.68	2.89	21
	Treat	1.68	1.85	23
	Total	2.63	2.58	44

Figure 2.



The next analysis investigated self reported pain intensity (VAS). Descriptive statistics are presented in Table 14.

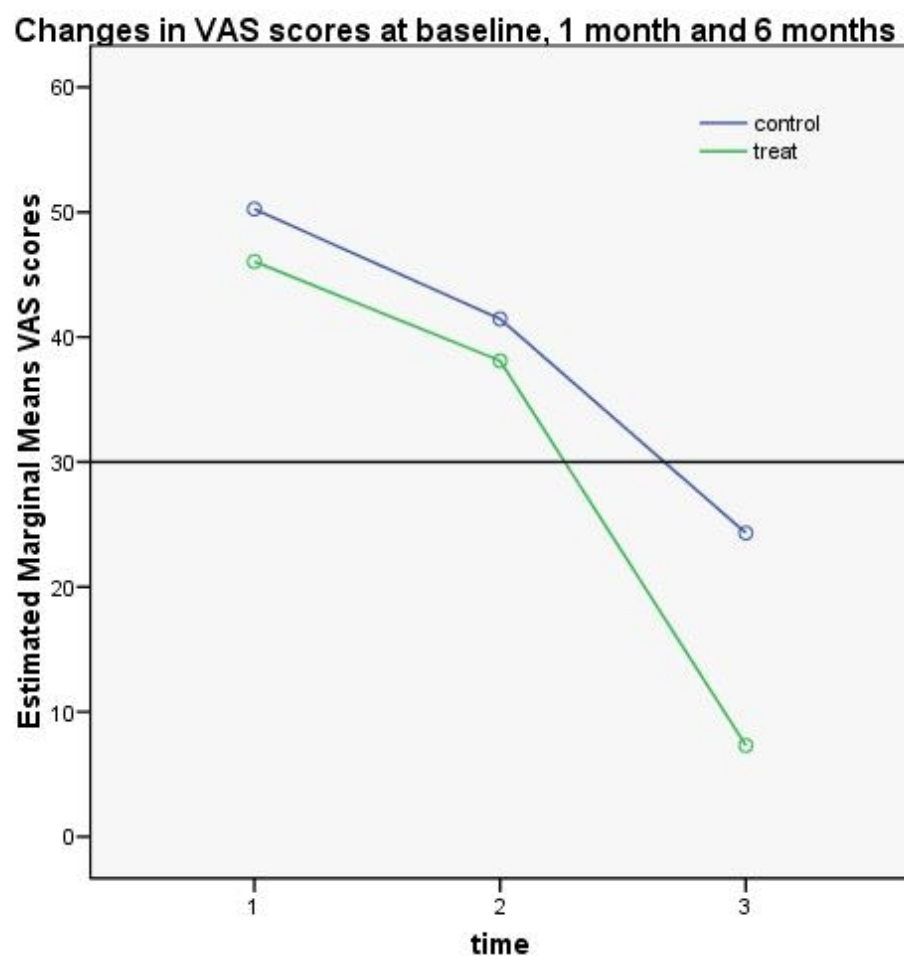
Table 14.**Descriptive statistics for VAS scores for time 1, time 2 and time 3.**

	Group	Mean	SD	N
VAS 1	Control	50.25	19.37	21
	Treat	46.05	18.41	23
	Total	48.05	17.77	44
VAS 2	Control	41.45	23.94	21
	Treat	38.10	18.80	23
	Total	39.70	21.21	44
VAS 3	Control	24.32	21.34	21
	Treat	7.31	5.68	23
	Total	15.43	17.38	44

There was a significant effect for time (Wilk's Lambda=.281, $F(2, 41)=39.12$, $p<.05$, partial eta squared=.656). The decrease in self reported pain intensity on VAS scores across the three, different time periods is illustrated in Figure 3. Figure 3 indicates a trend for a greater improvement in VAS scores in the intervention group compared to controls between times 2 and 3. The interaction effect, indicating whether the changes in scores over time were the same for the two different study groups, did not reach significance ($p=.067$), and the effect size was small (partial eta squared =.124). There was no statistically significant main effect for study group [$F=3.332$, $p=.075$], confirming there were no significant, between group differences in the observed improvements in VAS scores.

This supports the research prediction that both study groups would report significantly improved pain symptoms over time.

Figure 3.



The third analysis investigated the dependent variable PCS, a summary measure of physical health and well being as measured by the SF-12v2. Means and SDs for PCS scores at times 1, 2 and 3 are presented in Table 15.

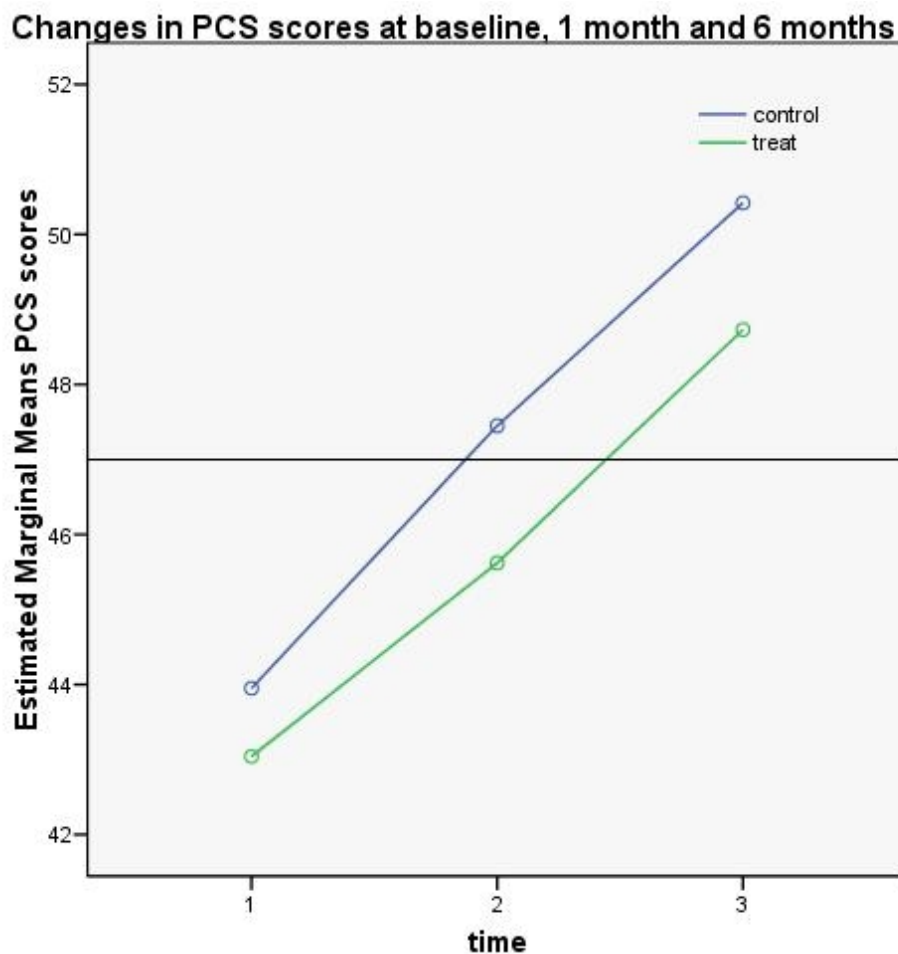
Table 15.**Means and SDs for PCS scores at times 1, 2 and 3.**

	Group	Mean	SD	N
PCS 1	Control	43.95	5.71	21
	Treat	43.04	5.06	23
	Total	43.48	5.33	44
PCS 2	Control	47.45	4.97	21
	Treat	45.62	6.12	23
	Total	46.50	5.61	44
PCS 3	Control	50.42	6.26	21
	Treat	48.73	5.55	23
	Total	49.54	5.89	44

There was a significant effect for time (Wilk's Lambda=.561, $F(2, 41)=16.056$, $p<.05$, partial eta squared=.439). The improvement in PCS scores over time is illustrated in Figure 4. The interaction effect, indicating whether the changes in scores over time were the same for the two different study groups, did not reach significance ($p=.899$).

There was no statistically significant main effect for study group [$F=1.305$, $p=.260$, partial eta squared=.030], confirming there were no significant between group differences in the observed improvements in PCS scores. This finding does not support Hypothesis 2, which predicted the intervention group would show significantly better scores on both the PCS and the MCS measures, post intervention, compared to controls. The MCS results are reported below.

Figure 4.



The fourth analysis was conducted on the MCS scores, a summary measure of mental health and well being as measured by the SF-12v2. The means and deviations are presented in Table 16. There was a significant effect for time (Wilk's Lambda=.753, $F(2, 41)=6.720$, $p=.003$, partial eta squared=.247). The improvement in MCS scores over time is illustrated in Figure 5. The graph suggests a trend for initially faster improvement in mental health and well being for the intervention group. The interaction effect, indicating whether the changes in scores over time were the same for the two different study groups, did not reach significance ($p=.899$).

There was no statistically significant main effect for study group ($F=.289$, $p=.751$, partial eta squared=.014), confirming there was no significant between group difference in the changes in MCS scores.

Table 16.

Means and SDs for MCS scores at times 1, 2 and 3.

	Group	Mean	SD	N
MCS 1	Control	40.45	6.52	21
	Treat	39.64	6.44	23
	Total	40.02	6.411	44
MCS 2	Control	43.30	3.37	21
	Treat	43.99	6.27	23
	Total	43.67	6.25	44
MCS 3	Control	44.05	5.57	21
	Treat	44.00	5.93	23
	Total	44.03	5.69	44

The hypothesis that, compared to the control group, PCS and MCS scores in the intervention group would improve significantly over time is not supported by the results. It is concluded that Null Hypothesis 2 should be accepted.

Finally, a post hoc analysis was conducted to compare RDQ scores between the control and the intervention arm at times 2 and 3, using an independent t-test at times 2 and 3. The mixed between-within subjects analysis of variance demonstrates there is a significant difference between the two groups' means. However, it does not show where that difference lies. At time 2 (at one month follow up), there was a significant difference in RDQ scores for controls ($M=5.25$, $SD=3.16$) and intervention participants ($M=2.46$, $SD=1.85$); $t=3.52$, $p=.001$. At time 3 (at six months' follow up), there was also a significant difference between controls ($M=3.68$, $SD=2.89$) and intervention participants ($M=1.68$, $SD=1.85$); $t=2.71$, $p=.011$.

The post hoc analyses show that significant improvements in back pain specific functioning for the intervention group versus controls found at one month are maintained, slightly attenuated, at six months.

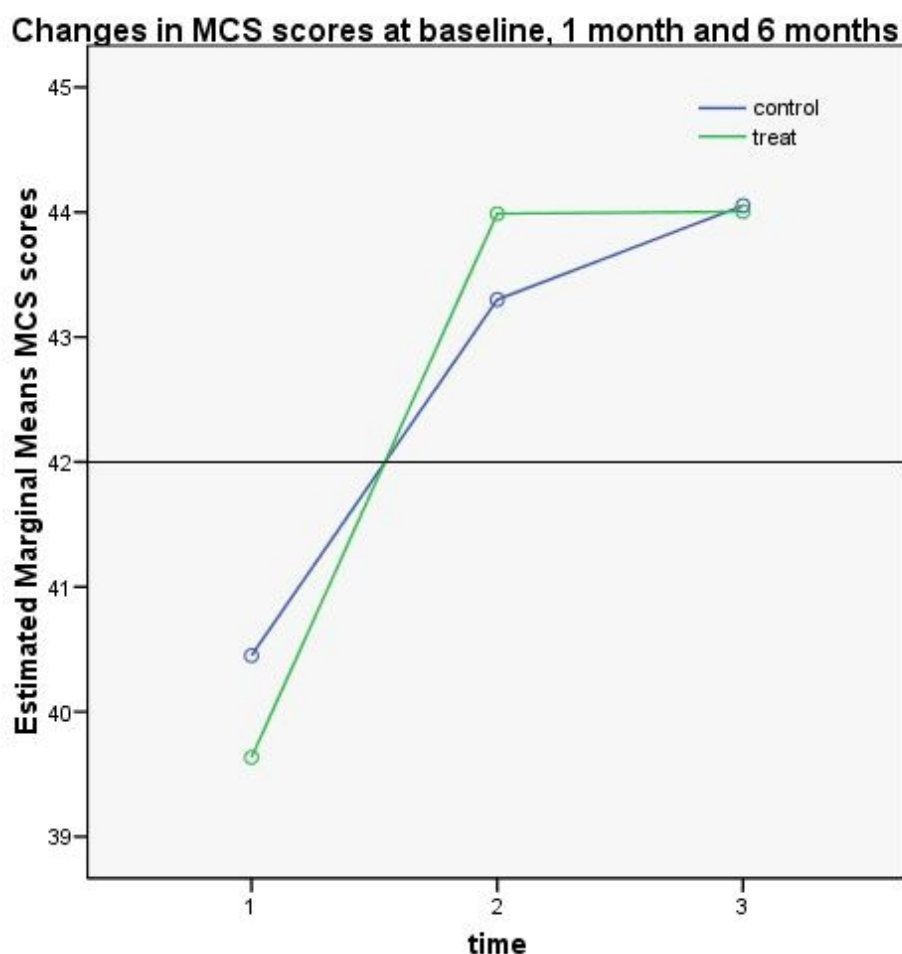


Figure 5.

No adverse side effects of using the self help audio programmes were reported by any of the participants in the intervention arm of the study.

6.4.4. Discussion of the results

The pragmatic, randomised controlled trial of the effectiveness of self help, audio CDs for early, non-specific low back pain demonstrated significant improvements in back pain specific functioning at one month in the intervention arm compared to controls. A significant difference between the study groups' RDQ scores was maintained at six months. Trends were observed for greater improvements in pain intensity between one month and six months and for greater improvements in mental health and well being at one month follow up for participants using a self help CD versus

controls but these trends were not statistically significant. Both study groups demonstrated significant improvements in scores on all outcome measures between baseline and the six months.

It was expected that all participants would, on average, show improvements in their back pain symptoms over the six month follow up period for the study, reflecting the variable course of acute episodes of back pain which may fluctuate, resolve spontaneously and recur over time (Croft et al., 1998). Pengel et al. (2003) reported significant improvements in pain and disability within one month and further improvements at follow up at three months, which is similar to the findings of significant improvements in all outcome measures for both groups that are reported here. The findings by Pengel et al. (2003) that lower levels of pain and disability persisted were also similar to the findings of the present study, in which significantly reduced but residual pain and disability were evident at six months. The mean RDQ score for controls at six months was 3.7 (SD 2.9) and the mean VAS score was 24.3 (SD 21.3). The large standard deviations illustrate the wide variation in prognosis for acute low back pain episodes; very few participants reported complete resolution of painful symptoms at six month (4/44) while some 71% of the total sample reported incomplete recovery from back pain related functional symptoms at six months. Participants reported in all cases that symptoms reported at six months related to the original episode; symptoms at follow up did not reflect resolution of an episode followed by recurrence. Ongoing, back related problems among participants in research studies that did not use stopping consulting or return to work at the main outcomes have been reported previously (Croft et al., 1998; Thomas et al., 1999; Jones et al., 2006). Nonetheless, the residual symptoms in this study were, on average, mild, perhaps reflecting the initially mild to moderate symptoms of pain and disability that were typically evident in this community study sample at baseline. It might be speculated that those with more severe, back pain symptoms would choose to consult a doctor. It is also not clear that the findings from a community sample can be generalised to primary care patients.

While significant differences in back pain specific functioning were observed between the CD intervention group and the control group, the predicted, significant between group differences in outcomes in the domains of mental health and well being and physical health and well being were

not realised. This might suggest that condition specific measures of physical symptoms, such as the RDQ for back pain, may capture problems experienced by people with back pain that general scales of physical well being, such as the PCS of the SF-12v2, may fail to capture. Both study groups demonstrated significant improvements as measured by the mental health and well being scale of the SF-12v2. There was a trend for greater and faster improvement within the first month observed in the intervention group, although this trend was not significantly better than the observed improvement on this measure in the control group. Improvement in mental health and well being over time may influence self reported functional disability; in this study, both mood (as measured by the PHQ-9) and pain intensity were found to make unique and independent contributions to the baseline RDQ scores, with mood making the stronger contribution (PHQ-9 standardised Beta coefficient 0.566; $p < 0.5$). This accords with earlier, published work that has described an association between acute, non-specific low back pain and depressive mood (Croft et al., 1995; Larson et al., 2004; Pincus et al., 2006; Mayer et al., 2007).

The results of the trial indicate that a three week, self help, audio CD, providing information, reassurance and encouragement for early, self management of non-specific low back, can significantly improve back pain specific functional outcomes at one and six months. Implementing an intervention that can improve outcome measures in the short term may help reduce the numbers of people – variously estimated to be between 5 - 10% of the total (van Tulder & Koes, 2006) – who decline from acute, non-specific low back pain to chronic pain and disability (Nic Lochlainn et al., 2008). It is less clear whether using a self help, audio CD may influence the recurrence of acute back pain episodes, evidence for which would require a trial with a longer follow up period.

It may be assumed that members of the public who volunteer to join research into self help, audio CDs are motivated to engage with self help to manage early back pain. This study does not illuminate why these individuals were motivated to join the research. The majority of the participants (37/44) reported having previous experiences of acute back pain episodes; prior experience of repeated episodes may perhaps have been a factor. It is also noted that baseline,

depressive symptoms, between mild and moderate in severity, as assessed by the PHQ-9, were prevalent in the research sample (see Tables 11 and 12). It may be speculated that mood might also influence approaches to self management. Given the heterogeneity of a community sample and the heterogeneity of the condition, in addition to the likelihood of fluctuating psychosocial factors in the acute phases of back pain (Dunn & Croft, 2006), motivations to join a self help research project are likely to be varied. An assumption that these recruits were motivated to engage with the intervention programme is however supported by the adherence rate observed in this trial; of the 23 participants who were randomised into the intervention group, only one was lost to follow up (two lost to follow up in the control group). This compares favourably with the collection of follow up data achieved in the CBT based intervention to enhance acute back pain management in the U.S.A. reported by Damush et al. (2002; 2003). Their work was undertaken with an urban population sample, many of whom had prior experience of low back pain. In an adjustment to the planned, intervention delivery, some 60% of the participants in the research by Damush and colleagues received the self help intervention by audiotapes posted to their homes. The authors reported final, follow up data (at 12 months) for only 66% of the study sample. Nonetheless, recruitment into the current trial was found to be very slow and patchy, despite the researcher experimenting with successive strategies in an effort to access eligible participants, including approaching large institutions with many employees, posting fliers and advertising in local newspapers.

The target sample size of 74 was not achieved. It is possible that the a priori, sample size calculation may have overestimated the number of participants required. The study power, with a total of 44 recruits, was adequate to detect a significant, between group difference with respect to back pain specific functioning, despite the magnitude of the effect size, as had been anticipated, being small. A possible explanation for this in retrospect is the influence on the sample size calculation of the input parameter, correlations among repeated measures (see Section 6.3.6.). This parameter relates to the correlations between the measurements obtained at each of the study time points. If the measurements were more highly correlated with one another than assumed in the default statistic supplied by the G*Power software, then this would tend to lead to

an overestimate of the numbers of participants needed, given a study power set at 80% and alpha set at .05. Without prior knowledge of the actual correlation statistics, it is preferable to take the conservative, default correlation statistic in the calculation programme, which assumes the correlations are not high. Otherwise one risks planning a study that may be underpowered to detect any effects, which would then make it impossible to interpret non-significant findings (Simon, 2006).

It had been hoped that carrying out the trial of self help CD effectiveness in the community, rather than in primary care, would markedly improve recruitment into the research. This was not the case. Life time prevalence for low back in developed countries has been variously estimated to be between 49% and 84% (Dionne, 1999; Koes et al., 2006). While it is accepted that self help programmes will not be appealing nor necessarily appropriate for everyone (DoH, 2005a; DoH, 2005b), the discrepancy between the theoretically very large pool of recruits of adults in the general population with acute, non-specific low back pain and the apparent lack of interest from the public in a free, self help, audio CD presented a puzzle for the researcher. It made the researcher wonder why it was that so few people with early back pain seemed to be interested in using free, audio CDs to learn how to help themselves to manage the condition. Despite the encouraging, preliminary results for the effectiveness of the CD programmes reported here, a self help intervention for early back pain would not be "effective" in practice if most people affected by early back pain were not interested in using it. The observed difficulties with recruitment, firstly in primary care and, again, in the community, produced new research questions about who was and was not prepared to engage with self help for early back pain and why. It was hoped that exploring people's experiences of self help for non-specific back pain could augment the quantitative, effectiveness findings by illuminating some of the reasons for the recruitment problems experienced - and their implications for self help interventions for early back pain. Additional, qualitative research work to try to address such questions is reported in the following chapter, Chapter Seven.

Further discussion of the quantitative trial in relation to the existing literature, including the limitations of the study, is presented in the concluding, discussion chapter of the thesis, Chapter Eight.

7. Chapter Seven. IPA investigation.

7.1. Introduction

In this chapter, the debate about mixed study designs is discussed and it is argued that combined use of quantitative methodology and the qualitative methodology of Interpretative Phenomenological Analysis (IPA) is compatible with maintaining paradigmatic integrity for the social cognitive researcher. The suitability of IPA for an exploration of people's experiences of self help for back pain is explained. Advantages and disadvantages of computer mediated communication methods, particularly on-line focus groups and email interviewing, are discussed and their choice for data collection in this qualitative part of the study is justified. An account is given of an unsuccessful attempt to pursue data collection using an on-line focus group, followed by an account of the more successful use of email to interview study participants individually. Finally, the findings of the IPA analysis of participants' email interviews are presented and discussed.

7.2 The debate about mixed designs

Epistemological arguments have implications for both qualitative and quantitative researchers, from the choice of research question, through the study design and the research techniques selected to the presentation of findings – indeed, to what constitutes “findings” and by what criteria they should be judged. Traditionally, in quantitative research, the quality of research work is judged on criteria of internal and external validity and reliability, all notions linked to a world view that external, verifiable truths exist. Qualitative researchers have developed alternative criteria for assessing the quality of their studies, reflecting quite different theorising about the knower and the known and how knowledge is constructed. Notably, trustworthiness, credibility and accountability have been proposed as appropriate criteria for judging qualitative work and these are suggested to have equivalence to the criteria for quantitative research (Denzin & Lincoln, 1998). Study designs combining qualitative and quantitative methodologies can be embraced by some researchers while, for others, mixed study designs are irreconcilable with their ontological and epistemological positions.

Ontology is concerned with the nature of reality. Epistemology is theory of knowledge, or how we know the world. Methodology is a system of research procedures or techniques for acquiring knowledge. The conceptual framework that contains a researcher's ontological, epistemological and methodological premises may be termed a paradigm, or a basic set of beliefs which guides action (Denzin & Lincoln, 1998). According to Denzin & Lincoln (1998), qualitative research encompasses four, major paradigms (positivist and post positivist; constructivist-interpretive; critical; and feminist-post structural) and each of the paradigms can house within it a multiplicity of perspectives. For example, a feminist-post structural paradigm contains within it many, different feminist perspectives (Ramazanoglu, 1992).

Qualitative researchers can lay claim to a range of diverse research traditions, some of which were allied to particular disciplines in social science, such as phenomenology from philosophy and ethnography from social anthropology (Miller & Crabtree, 1999). Qualitative research is also "multi method". Studies variously employ, for example, participant observation, interviewing, focus groups and case studies. Further, there are multiple approaches to analysing the data generated by qualitative enquiry, including qualitative content analysis, grounded theory, IPA and discourse analysis. Given the multiplicity of perspectives within paradigms, research traditions, methods and approaches to data analysis, qualitative research can not be considered a single, homogeneous entity.

Nonetheless, there are characteristics that are associated with qualitative research generally. Induction underpins the design, fieldwork and analysis of most qualitative work (Hisada, 2003). Reflexivity and subjectivity are also important characteristics of qualitative studies. According to Hammersley & Atkinson (1995):

"...researchers will be shaped by their socio-historical locations, including the values and interests that these locations confer upon them." (p. 16)

By implication, no research endeavour can be an objective exercise. Accordingly, qualitative researchers often emphasise the relationship between the researcher and what the researcher is studying and the focus of qualitative enquiries is on processes and subjective meanings. Qualitative researchers may hold a world view that posits the existence of multiple realities that are created and negotiated. Because, in this view, there are no enduring, context free statements of “truth”, qualitative findings are situated in a specific time and place.

These general characteristics of qualitative research may be contrasted with distinctive features of the quantitative research endeavour, in which the focus is on variables and on measuring correlational or causal relationships between them. Quantitative research aspires to detached objectivity and aims to discover demonstrable, general rules and facts about a “real” world that exists outside any human constructions of it. Drawing distinctions between the general characteristics of qualitative and quantitative research has become the key feature of an epistemological debate that is known as the qualitative-quantitative debate (QQD) (Hammersley, 1996). The debate is typically framed in terms of opposites: relativist versus realist; subjective versus objective; inductive versus deductive; interpretive versus normative.

Some contributors to the QQD, for example, Oakley (2000), suggest that a dualistic approach serves to exaggerate differences between qualitative and quantitative research. The dualistic distinction between induction versus deduction may be exaggerated given that in any research field there could be movement from theories to data as well as movement from data to theories (Hammersley, 1992). Further, the discovery of Heisenberg’s Uncertainty Principle in quantum physics means that quantitative scientists have long since recognised there is an interaction between the knower and that which is known, hence the aim of entirely objective research is unattainable. Westmarland (2001) argues that beliefs about objectivity in quantitative research have been displaced by recognition of the subjective nature of knowledge and hence exposed the “false” dichotomy between qualitative and quantitative research. However, Westmarland (2001) does not explicitly discuss how her choice of research area, study designs and eclectic methodologies relate to wider, philosophical issues, including to theory of knowledge, and she fails

to account for features of qualitative research other than subjectivity, for example, researcher reflexivity.

Despite the efforts of some researchers to minimise the distance between qualitative and quantitative research positions, ontological, epistemological and methodological differences remain. This suggests any mixed study design should be explicitly justified, perhaps especially by qualitative researchers for whom reflexivity is central to the research process. A realist ontology logically leads to a quantitative, epistemological stance that some truthful knowledge is potentially discoverable. A relativist ontology, on the other hand, leads to a qualitative epistemological stance of knowledge being generated and contextual. Specifically, in the constructivist paradigm, a relativist ontology that denies the existence of a single, “true” reality connects to a subjectivist epistemology, that is, that understandings are constructed through dynamic interaction, and thence to a naturalistic methodology. The social constructivist theorists Gergen & Gergen (1991) hold there are no “real world” referents. People’s accounts of the world:

“... are not viewed as the external expression of the speaker’s internal processes (such as intention), but as an expression of relationships among persons.” (Gergen & Gergen, 1991. p. 78)

The social constructivist view does not invoke the existence of psychological constructs such as intentions and beliefs, whereas cognitions such as these are generally assumed to be modifiable entities in mainstream health psychology that has a tradition of employing quantitative methodologies and methods (Crossley, 2000).

From a qualitative perspective such as that of Gergen & Gergen, the appropriate focus of research is not people’s idiosyncratic mental processes but their interpretative repertoires or discourses, and it follows that the appropriate methodology is discourse analysis (DA). DA is a methodology that is prominent in an emerging critical health psychology, which, while embracing a range of perspectives and aims, can be outlined as an academic endeavour to question the socio-political values and assumptions underlying mainstream health psychology (Crossley, 2000). Rejecting a

study design with a quantitative component would be a logical position for a social constructivist to adopt. Equally, it would be internally inconsistent within a social constructivist paradigm to employ the qualitative methodology of IPA, in which the existence of modifiable, cognitive entities is assumed. However, for a social constructivist's qualitative colleague who works within a social cognitive framework, paradigmatic contradictions do not necessarily arise from the methodology of IPA nor the use of mixed designs. These apparently contradictory outcomes reflect the diverse, philosophical stances within the heterogeneous body of qualitative researchers.

In practice, many researchers do employ both qualitative and quantitative methodologies in research designs. For some, the question of mixed designs may be less a philosophical one than a pragmatic one. The dualistic labelling familiar from the QQD can be seen to be mirrored by internal, dualistic labelling within the qualitative research community. In this instance, labelling describes qualitative researchers as either “purists”, firmly wedded to their epistemological stance and to all that flows to and from that, or as “pragmatists”, who cast themselves as more progressive, claiming it is time to move beyond epistemological and methodological arguments and simply to use whichever designs and methods best suit the research question (Becker, 2004). A third group has been identified in addition to the pragmatists and purists. According to a study by Rabinowitz & Weseen (1997), instead of engaging in meaningful debate about ontology, epistemology and methodology to arrive at a research paradigm, some qualitative researchers' pick of paradigm is directed more by such influences as workplace politics, peer pressure or personal preference.

Presumably addressing those researchers who are still concerned about paradigmatic integrity, Becker (2004) has called for a transformation of epistemology to turn it from a philosophical discipline that settles questions by reasoning from first principles into a practical discipline that settles questions empirically. Implicit in the call for empirical pragmatism is that the links that logically connect ontology, epistemology and methodology, however imperfectly such links may currently be conceptualised or put into practice by particular researchers, could be further weakened. Similarly, Hisada (2003) recommends the qualitative researcher to be “bricoleur” and to

favour flexibility in qualitative research over “purist” attitudes towards epistemology and methodology. These appeals appear seriously to challenge Lincoln’s assertion that:

“The adoption of a paradigm literally permeates every act even tangentially associated with inquiry...” (1990, p. 18)

Nonetheless, as discussed here, the paradigmatic difficulties posed, if any, depend on the particular researcher; for some, but not for others, adopting bricolage and using mixed study designs may be simultaneously pragmatic and philosophically coherent.

The existence of a real world independent of our perceptions and interpretations of it is not refuted by this author, nor is the constructed nature of those perceptions and interpretations. Thus a relativist, subjective and interpretative framework for understanding aspects of human psychology is incorporated into a broadly realist ontology. Bridging social cognitive and social constructivist paradigms are narrative theorists such as Bruner (1990). Making a distinction between paradigmatic and narrative thinking, Bruner makes progress towards a dynamic system in which both the individual with cognitions and socio-cultural discourse have a place. Phenomenologist psychologists might also argue that individuals’ experiences are influenced by their idiosyncratic mental processes while not rejecting the existence of external objects and the role of external influences, such as societal structures and culture. The phenomenologist Burkitt (1999) writes:

“The body image and self image we develop is based on the sense of being embodied and the way in which this experience is mediated by culture.” (p. 147)

A phenomenological approach to the human body draws distinctions between co-existing dimensions of the subjective experience of embodiment. The term “subjective body” refers to the experience of having a body that is unselfconsciously engaged in daily activities and tasks, without reflection. This is sometimes described as the “lived body” and by Sartre (1969) as the body that is passed by in silence. The “objective body” refers to a conscious, perspective taking of the same physical body, either by others or by oneself. With the onset of pain or during illness, when the

body can no longer be 'passed by in silence' because of the disruption to normal functioning, one's consciousness of one's own body is likely to shift into greater awareness. Toombs (1993) describes this process as:

"The disruption of lived body causes the patient explicitly to attend to his or her body as body... The body is thus transformed from lived body to object-body." (p. 70-71)

A third dimension relates to the experience of bodily self consciousness that arises from the awareness of other people's judgements about us, based on our appearance. Van Manen (1990) describes this last dimension:

"For example, under the critical gaze the body may turn awkward, the motions appear clumsy, while under the admiring gaze the body surpasses its usual grace and its normal abilities." (p. 104)

Phenomenologists consider the physical body to be the vehicle through which people experience all of life's experiences and learn about themselves and others in the world (Merleau-Ponty, 1962). In a phenomenological approach, it is the interplay between a person's multiple, co-existing experiences of embodiment that leads to that individual's idiosyncratic understandings of the world - or, to frame it in social cognitive terms, to the formation of their cognitions.

In this thesis, it is accepted that human bodies are biological entities existing in an objectively real, physical environment. At the same time, it is accepted that the subjective meanings that are ascribed to both bodily and social experiences are constructed by individuals situated within particular cultures, historical periods, socio-economic circumstances and power relationships. That the objective and the subjective are somehow linked is an underlying assumption. Such an assumption is concordant with the social cognitive framework of mainstream health psychology, which presumes the existence of some relationship between people's physical bodies, their thoughts, feelings and beliefs about their bodies and the words they use to try to communicate with others about their bodies and their mental processes. In keeping with a social cognitive framework,

and divergent from DA, IPA methodology assumes that people experience mental cognitions related to their physical bodies and that those cognitions may be expressed, to some degree, through language. Thus while the social cognitive approach in health psychology has translated predominantly into quantitative and experimental research, appropriate, for instance, for assessing therapeutic interventions, there is no paradigmatic contradiction inherent in combining quantitative approaches with a qualitative, IPA approach; the latter also examines mental processes and behaviours but is concerned with gaining indirect access to research participants' lived experience, that is, to:

“... an ‘insider’s perspective’ of the topic under investigation.” (Smith et al., 1997, p. 69)

IPA has been employed in an increasing number of published studies in recent years and is a methodology that features strongly in the health psychology literature (Brocki & Wearden, 2006). Its selection for this study is based on its suitability for generating appropriate data to address the research question – how individuals construe self help in relation to living with non-specific low back pain – and its congruence with the overall epistemological and theoretical framework of this researcher and thesis. The quite different focus of the two research questions addressed in the thesis, whether self help audio CDs are effective in early back pain management and how back pain sufferers perceive self help in relation to back pain, are epistemologically compatible within a social cognitive framework but require different methodologies and methods to address them.

The first study is designed around an a priori hypothesis that an early, self help intervention will improve measurable, clinical outcomes in early back pain, such as back pain related functioning as measured by the RDQ. The principal question is not whether a particular individual will perceive benefit from pursuing self help management techniques but whether, on average, there are significant differences in measurable, clinical outcomes between early back pain sufferers using the self help CD and those not using it. Hence a quantitative, controlled trial of the effectiveness of the CD intervention is appropriate. The second study is an exploration of individuals' experiences of self help with the aim of illuminating some of the subjective processes that may impact on the

early use, or not, of self help for back pain. This investigation arose directly from the first study, in which it was found that recruitment to the early intervention trial posed significant difficulties. The slow uptake of a free, self help CD led the researcher to question why it might be that such a widespread condition produced so few individuals apparently interested in exploring ways to help themselves. For example, it was speculated that slow recruitment might reflect ongoing adherence to a biomedical model of back pain with attendant expectations that treatment for the condition should be given by a GP or other medical health professional. Alternatively, it was speculated, individuals may hold beliefs that having back pain was a normal part of life about which nothing could be done, or perhaps that an initial experience of back pain would be a quickly self limiting episode of discomfort with the expectation that, once the episode had resolved, they would be permanently “cured”. The aim of the second, qualitative study, therefore, was not to test a specific hypothesis but to explore people's personal accounts of back pain and self help, that is, to explore an “insider's perspective” on the topic.

Closer collaboration between quantitative and qualitative researchers is advocated by a number of health psychologists, such as Thompson et al. (2002) and Smith et al. (1997). Some psychologists suggest that quantitative research may operate more successfully at the “macro level” of constructing and testing psychological models and such work can be enhanced by “micro level”, qualitative research. By illuminating individuals' subjective experiences, the latter may reveal previously unrecognised processes that are at work within the macro level models. Smith (1996) advocates that psychologists should make use of IPA methodology to develop an existing tradition in the medical sociology literature of exploring what health related experiences mean to individuals. Over and above idiographic findings, IPA analyses may indicate targets for psychological intervention, for example, in chronic back pain (Osborne & Smith, 1998) and health promotion (Flowers et al., 1997), as well as potentially uncovering constructs absent from current psychological theories.

7.3. Theoretical background of IPA

IPA's roots lie in phenomenology, Husserlian hermeneutics and symbolic interactionism (Smith et al., 1997). The mathematician and philosopher Edmund Husserl (1859 – 1938) outlined phenomenology as a reflective study of the essence of consciousness as it is experienced from the first person viewpoint. Symbolic interactionism is related to phenomenology in that it is also concerned with first person viewpoints. It is a sociological theory developed in the 20th century in the U.S.A., which attempts to explain human behaviour as the outcome of the subjective meanings attached by individuals to other human beings, social situations, events and physical objects. The theory posits that social interactions are conducted through symbols, including language, that are created by human beings to refer to subjective perceptions of matters rather than to the objects or events themselves. As a sociological approach, it developed along separate lines from phenomenological branches of philosophy and, typically, has been employed by sociologists to investigate behaviours in smaller communities, for instance, among criminal groups. Hermeneutic pertains to interpreting and explaining language, traditionally written texts.

IPA is phenomenological because it explores people's perceptions of the world and their experiences in it (Giorgi & Giorgi, 2003; cf. Willig, 2001) and interpretative, or hermeneutic, in giving the researcher a key, interpretative role in making sense of people's subjective, spoken or written accounts (Palmer, 1969). According to Smith (2004), IPA involves a double hermeneutic in which the:

“... participant is trying to make sense of their personal and social world; the researcher is trying to make sense of the participant trying to make sense of their personal and social world.” (p. 40)

Whereas a phenomenological analysis is essentially a descriptive account of the first person viewpoint, the double hermeneutic in data analysis is distinctive of IPA. The aim of the ensuing qualitative study was not only to present individuals' accounts of their own interpretations of the role of self help in managing back pain but also for the researcher, working within a social cognitive framework, to relate themes identified in those accounts to psychological concepts found in the

existing literature. Hence the double hermeneutic methodology of IPA was selected for the qualitative data analysis.

7.4. IPA methods

Given the theoretical background and the idiographic, inductive and questioning nature of IPA (Smith, 2004), the most widely advocated and used method of data collection is the semi-structured interview. A schedule of open questions, supplemented by prompts if necessary, is designed to encourage the interviewees' personal reflections and to elicit extensive responses from them (Gillham, 2000). A semi-structured interview aims to ensure the researcher's agenda is addressed while retaining a sufficiently flexible structure to explore new areas of interest that may emerge during the interview. On occasions, IPA proponents favour a single question approach to interviewing, with any further questions from the interviewer stemming from the participant's response to a single, introductory question. It is not clear that this approach necessarily offers advantages over combining responsiveness to the interviewee's initial response with the option of asking supplementary, open questions previously prepared by the researcher. The single, general question may sometimes be more suited to an initial, exploratory investigation into subjective accounts of an experience not previously researched, that is, to a novel, research enquiry in which the researcher is "naive". In practice, many IPA researchers come to an IPA study with prior knowledge of the topic area and have formulated their own ideas and questions from which the rationale for carrying out the study has developed. In these situations, the IPA researcher uses "bracketing". Bracketing, also known to phenomenological theorists as *epoche*, may be described as a self aware act of suspending judgements about reality. For phenomenologists this might mean, for example, jettisoning subjective assumptions about what is held to be of importance by another human being and why. For IPA researchers, it refers particularly to the reflective process of bringing their own preconceptions about the research area to the fore and temporarily holding them to one side in order to conduct interviews and analyses with an open, questioning, non-judgemental mind. The iterative process of the IPA researcher moving between 'dwelling' with the data and interrogating the data has been described as a dance (Finlay, 2003).

Semi-structured interviews are typically conducted face to face, although some researchers have undertaken telephone and email interviewing (Brocki & Wearden, 2006). Other IPA authors, notably Flowers and colleagues (for example, Flowers et al., 2003) have presented a combination of focus group and individual interview data, while only focus group data have been presented elsewhere (for example, by Dunne & Quayle, 2001). The focus group method was defined by Morgan (1997) as a research technique to collect data from the interactions between people who had been brought together by a researcher to discuss a particular topic. Focus groups originated in market research in the 1940s, since which time they have been used in business studies, health related studies and social science research (Rezabek, 2000). In 2004 Smith described using focus groups for IPA as an “area ripe for exploration” (p. 50) while urging a degree of caution. Smith is concerned that the idiographic nature of IPA should not be lost and recommends parsing focus group data repeatedly, for individual narratives, group patterns and group dynamics.

7.4.1. Computer mediated communication

More recently, qualitative researchers have used computer technology to move the well established, face to face focus group into an on-line, “virtual” environment. The on-line focus group (OFG) is “an emerging qualitative method” (Oringderff, 2004, p. 2). An OFG may also sometimes be referred to as a virtual focus group (Murray, 1997). Similar to the face to face focus groups from which they are derived, OFGs consist of groups of individuals, purposefully selected by a researcher, who have volunteered to explore their views and the influences that have informed those views (Mann et al., 2000). Similar to the semi-structured interview, a focus group discussion is structured and moderated by a researcher while retaining a sufficiently flexible format to allow new topics to be explored as they emerge. Unlike a semi-structured interview, in which the data consist of individuals' subjective accounts, OFG analysis is also concerned with the interactions between members of the discussion group.

Research discussion groups that are hosted on the Internet may be conducted asynchronously or synchronously. A synchronous OFG is a real time discussion, in which all of the group members

are on-line simultaneously at a specified time. It would normally make use of on-line chat tools. An asynchronous OFG is one in which there is a longer, defined study period, during which participants read each other's postings on-line and post their own contributions to the developing discussion at times that suit them. Asynchronous OFGs usually employ discussion boards. An asynchronous OFG will generally be active for a period of some weeks, such as a group discussion about migraine, which was open to participants for five weeks (Moloney et al., 2003). The longer study time allows researchers to probe responses for clarification and gives participants opportunities to review and develop their own and others' postings. The relatively slower pace of asynchronous OFGs may make them easier to moderate more effectively than synchronous OFGs (Stewart & Williams, 2005).

An alternative computer mediated communication (CMC) method is email interviewing. In common with virtual focus groups, on-line interviews allow researchers to work with geographically dispersed participants (Oringderff, 2004) and also to include participants for whom leaving their houses might be difficult for physical or psychological reasons. For instance, CMC studies have been conducted with people with physical disabilities (Turney & Pocknee, 2005), who are housebound (Denscombe, 2003) and who are seriously ill (Im & Chee, 2006), as well as with participants who are in politically sensitive and potentially dangerous situations (Mann & Stewart, 2000). Using a CMC method may also facilitate the recruitment of busy, professional participants who might not otherwise be available to take part in research studies (Boshoff et al., 2005). Again, email interviews may be conducted synchronously (both the researcher and the participant on-line and working from their respective computers simultaneously) or asynchronously. Both CMC methods are attractive to researchers because they are inexpensive and circumvent transcription time and errors (Bloor et al., 2001) while, for participants, asynchronous on-line research in particular - where participants can choose when and for how long to be logged on - offers flexibility and convenience.

Accessing recruits who may be more difficult to enrol into traditional, face to face studies is an advantage of CMC methods. Nonetheless, advocates of Internet based research may overstate its

ability to support access to diverse research participants across geographical boundaries and time zones. Global Internet usage is likely continue to develop at speed, however, to date there remain marked, international inequalities in terms of technical infrastructure, the local availability of computer hardware and software and the financial costs for Internet users. According to the World Internet usage Statistics, North America has the highest Internet penetration rate. In December 2007, over 70% of North America's population had Internet access available to them, and the figure for Europe was 43.4%. These figures might be contrasted with the lowest Internet penetration rate reported at the end of 2007, under 5%, found in Africa (<http://www.internetworldstats.com/stats.htm>). According to Thurlow et al. (2004), the so called "international" knowledge economy involves only one per cent of the world's population. These authors noted that approximately half of the world's population had not used a telephone, far less a personal computer (Thurlow et al., 2004).

In addition to persisting inequalities in the availability of the Internet, which limit the international diversity of on-line research recruits and affect the data that may be gathered on-line, there are international inequalities with respect to Internet censorship. For example, there is government censorship of the Internet in Singapore, the Gulf states and China (Rodriguez, 2000; Grossman, 1997). It would be naive to assume that Internet access automatically equated with the freedom to express oneself openly and honestly in on-line research. Further, the English language remains the dominant language on the Internet, which may also have implications for communicating with and collecting rich data from a diverse range of international research participants.

Whether or not these differences, collectively referred to as the digital divide, present barriers to carrying out a credible, trustworthy, accountable CMC research project depends on the nature of the particular study. In this instance, the international digital divide did not pose drawbacks, however, at a national level it is acknowledged there are likely to be trends in Internet use within the U.K. that may vary, for example, by age, sex, ethnicity or income. Any population biases present in Internet users will be imported into on-line research samples (Bloor et al., 2001). The present study sought to reach U.K. wide participants who were English speakers and whose

condition, non-specific low back pain, was likely to make the prospect of travelling to a face to face, research venue unappealing or unduly onerous. It was noted that during the initial phase of the research for this thesis (the pilot evaluation of the acceptability to patients of new, self help audio CDs), four potential recruits had cited the need to travel to local research appointments as their reason for declining to enrol. Thus the advantages of CMC methods for a back pain population who might be discouraged from research participation by any travel requirement, combined with the benefits to the researcher of increased geographical reach within the U.K., financial savings (for costs for travel expenses and venue hire) and of having data produced in a format ready for analysis, without transcribing, were judged together to outweigh the potential disadvantage of losing access to potential recruits who were not computer users. The latter may have been viewed as a greater disadvantage were it not an IPA study in which the idiographic narrative remains of primary importance throughout. IPA sampling is discussed further in section 7.4.2.

Table 17: Advantages and disadvantages of CMC methods

Potential Advantages of CMC Methods	Potential Disadvantages of CMC Methods
Access to geographically dispersed participants	International inequalities, the “digital divide”
Access to hard to recruit individuals and groups	Excludes illiterate/IT illiterate members of population
Financial savings for researcher	Less initial familiarity with data?
Avoids need to transcribe data	May pose problems for rapport building
May reduce interviewer effect	Authenticity/true identities of participants
Convenience and flexibility for participants (particularly with asynchronous CMC)	

Potential advantages and disadvantages of CMC methods are presented in Table 17. Some potential disadvantages of CMC methods are particularly relevant to on-line research conducted in real time. For instance, synchronous OFGs are likely to require a fairly high degree of IT familiarity and technical competence from participants if they are to deal comfortably and in a timely manner

with using chat room tools or conferencing software. Typing speeds may also present problems, with slower participants perhaps finding it hard to keep pace with a real time discussion and contributing less than they might have wished. Email interviewing, either using the body of the email or Word attachments, is likely to present a more familiar technological environment to any regular computer user with email. With both real time, synchronous methods and with asynchronous methods, participants may be experiencing technical difficulties or personal distractions of which the OFG moderator or on-line interviewer is unaware, however, an asynchronous study allows both the participant and the researcher greater flexibility in when to contribute and more time in which to resolve any difficulties. Hence an asynchronous method was chosen by this researcher. Notwithstanding, a researcher conducting an asynchronous on-line study still has no visual cues to interpret participants' silences and may therefore fail to respond as appropriately to the interviewee as they might have done in a face to face situation.

Face to face communication normally includes the exchange of multiple, interpersonal cues, from personal appearance and dress, body language, gestures, eye contact, facial expressions and tone of voice and delivery speed. Whether the loss of these may be categorised as a potential advantage of CMC methods or a potential disadvantage is contested. Some authors (for example, Chen & Hinton, 1999) argue that taking part in on-line research demands greater motivation and engagement in the research from participants than would be required in a conventional, face to face setting. It has also been suggested that the absence of face to face cues and reliance upon only written text can result in more detached, less personal on-line communications and adversely influence the quality of research data gathered there (Walston & Lissitz, 2000). However, being able to interact, unseen, with others in a virtual environment may encourage less confident and less vocal research recruits to have a “voice” through their computers and so generate research data that would not otherwise have been realised (Mann & Stewart, 2000; Meho, 2006). Also, many computer users are familiar with on-line conventions for conveying feelings to accompany their typed text, including: emotional icons (“emoticons”), to indicate humour, pleasure, disappointment and so forth; paralinguistic expressions, such as “lol” (laugh out loud); and using capital letters to denote emphasis. All such supplementary text, if used by participants, could inform the analysis of research data collected from computer generated text.

The distance and anonymity offered by Internet communication may be thought to minimise any prejudice, biases or alienation between research group participants and between recruits and researchers and so be more conducive to personal disclosure (Reid & Reid, 2005), hence enriching research data quality.

According to Adams et al. (2005):

“If we are protected by the anonymity of the Internet, it is easier to tell another about ourselves, find common group, and express usually inhibited parts of ourselves.” (p. 1294)

Similarly, Poster contends that the absence of visual information about social status, gender, age and ethnicity leads to greater interpersonal candidness in the virtual environment (Poster, 1995). In the opinion of Reid & Reid (2005), CMC may produce less voluminous but superior quality data. IPA analyses of email interviews have been reported in published studies in health psychology by Turner & Coyle (2000), Murray (2004) and Murray & Harrison (2004). Murray (2004) carried out a combination of face to face interviews and email interviews and reported that the on-line interviewees' data were both more focussed and more frank because, Murray suggests, the on-line participants had more time to reflect before making their responses.

A recent IPA study by Adams et al. (2005) was premised on the anonymity of OFGs making them particularly suited to self expression, offering new opportunities for research into "taboo" topics with vulnerable participants. These authors analysed data from two OFGs, both with members recruited from an existing Internet site for young people who self harm. Adams et al. (2005) reported that four participants elected to be interviewed individually by email, rather than joining the on-line, group discussions. Subsequently, the group and interview data were jointly analysed but the authors did not discuss how, if at all, the different methods of data collection influenced the data generated nor their analysis. In this study, both virtual discussion groups were disrupted by inappropriate postings by people who were not officially taking part in the self harm study. This appears to raise serious ethical concerns regarding some OFG research, especially where it concerns vulnerable people. However, the problem of on-line intruders into an open research area could be overcome by using a password-protected, closed discussion forum, for instance, a discussion board hosted on a university's Virtual Learning Environment (VLE).

Given that traditional guidance for successful qualitative research methods (for example, interviewing, Gillham, 2000) usually advises paying close attention to visual and paralinguistic cues to engender feelings of trust between researcher and participant, it would seem CMC methods require, at the least, that the researcher should reflect on ways to minimise the loss of face to face strategies for rapport building. O'Connor & Madge (2001) reported that email exchanges prior to their on-line interview study helped to create an initial rapport between researchers and

participants. New parents taking part in the O'Conner & Madge (2001) study were invited to visit a specially created website that gave information about the study and had photographs to "introduce" the researchers visually to their on-line interviewees. Kivits (2005) reported that she chose to exchange general, personal information in the course of her email interviews. This was a deliberate strategy that she adopted in an attempt to develop an on-line relationship with each of her participants and to encourage disclosure. Other researchers, such as Orgad (2005), suggest reflecting on the potential impact of other aspects of conducting CMC research, such as whether or not to use an official, university email address or a personal email address, depending on the nature of the on-line enquiry. The techniques used by this researcher are discussed in the report of the study (section 7.7.4).

In addition to questions about how to build and maintain rapport on-line, a concern for researchers using CMC methods can be the question of the true identities of those taking part in the research (Greenbaum, 2002). A researcher's inability to verify the authenticity of on-line participants may not necessarily invalidate research conducted in cyberspace and the likelihood of enrolling recruits who are not whom they claim to be - and the impact of this on findings - will vary according to different enquiries. Concerns about verification of participants' authenticity were reduced in the case of the on-line study reported here because the interviewees were recruited from the existing members' mailing list of a national back pain charity, BackCare. In this way, reaching appropriate, potential recruits was simplified because, it was assumed, subscribers to BackCare were highly likely to be bona fide members of the population of interest, that is, people in the U.K. with personal experience of back pain.

7.4.2. IPA samples

In an IPA study, participants are a purposive sample, selected because of their relevant, personal experience. Purposive sampling in IPA may be contrasted with grounded theory, which would typically use theoretical sampling. Grounded theory aims to work from qualitative data to develop new, bottom up theory by achieving "saturation" of the emerging themes. That aim guides the

ongoing recruitment of new participants and/or employing different methods of data collection (Wimpenny & Gass, 2000). Triangulation, through using different participants or data collection methods, does not play an equivalently important role in IPA where the emphasis throughout remains on discussing idiographic findings in relation to the existing psychological literature. Some qualitative researchers may adopt triangulation techniques in an effort to enhance further the quality of their studies, perhaps particularly with regard to ongoing debates about qualitative findings and external validity (Gilchrist & Williams, 1999). However, a qualitative researcher might also argue that, rather than triangulating to establish commonalities between perspectives, a multiplicity of simultaneous, different perspectives should be maintained; in the opinion of Breuer & Roth, it is this plethora of perspectives that provides the richest source for knowledge production through the research process (Breuer & Roth, 2003).

That IPA does not aspire to use triangulation or samples that are representative of the whole population of interest – indeed, the parameters of the population may not be known – has clear implications for claims about the external validity, or generalisability, of findings. IPA findings may be specific to the particular group of individuals sampled, who are representative only in as much they have personal experience of the topic being investigated. Salmon (2003) suggests that while claims to generalisability may be abandoned in qualitative research, it is not always clear what ought replace them. Others (for instance, Duncan et al., 2001; Touroni & Coyle, 2002) argue that knowledge can be advanced through detailed, qualitative analyses of small groups of individuals, which can produce useful insights into subjective experiences and processes. According to Smith & Osborn (2003), idiographic, IPA findings may subsequently lead to making claims for larger populations. Nonetheless, any claims for generalisation from IPA samples should be made with caution.

In an IPA analysis, the idiographic account is paramount, however, having more than one participant's account allows the researcher to discuss the ways in which several, idiographic accounts both converge and diverge. Exploring themes common to the group does not imply “saturation” of the identified theme nor purport to be the only interpretation of it. Rather, IPA gives

weight to each subjective account of the phenomenon while also giving the researcher with multiple participants an opportunity to reflect upon what might underlie any commonalities that become apparent. The latter in particular may help illuminate socio-cultural contexts and processes relevant to the topic being researched (Shaw, 2001).

Characteristics of IPA research are summarised in Box 4.

Box 4. Characteristics of IPA research.**Adapted from Reid et al. (2005)**

- IPA is inductive
- Participants are recruited for their personal expertise in the phenomenon under investigation
- IPA analysis is rigorous and systematic to structure and simplify the data
- Analyses retain an idiographic focus while also giving an account of what is shared by participants
- Successful analyses are interpretative, transparent and plausible
- IPA researchers should practise reflexivity throughout the process

Because of its commitment to detailed, idiographic analysis, IPA sample sizes are normally small (Reid et al., 2005). For many published studies, this has been between five and 10 participants. Single case studies have also been recommended (Smith, 2004) but, as discussed above, analysing several accounts allows researchers to combine aspects of data that are unique to an individual with an analysis of themes that emerge as common to the group.

The process of carrying out a rigorous and systematic IPA analysis, whilst not prescriptive, has been clearly described (Willig, 2001; Smith et al., 1999) and will guide the IPA analysis in this thesis. The procedures followed are made explicit in the report of the email interview study that follows in section 7.7.

7.5. On-line research methods

The diversity of on-line methods and research topics has led to various views on what constitute acceptable, ethical practices in CMC research. A covert, on-line researcher investigating an existing Internet community will face quite different ethical dilemmas from the researcher

interviewing self selected participants by email, for instance. It seems reasonable to assume that the same principles of respecting research participants' autonomy and welfare and avoiding doing harm should apply equally whether the research is conducted off-line or on-line (BPS, 2007). Important issues to consider in CMC research might include: intellectual property rights; the use of deception; informed consent from participants, including their right to withdraw from any research; confidentiality and protecting individuals' anonymity; communication protocols to prevent aggressive or offensive behaviour on-line ("netiquette"); and procedures for researchers to provide CMC research participants with feedback on the findings. More recently new, ethical guidelines for on-line researchers have become available, while still acknowledging a need for flexibility in their practical application (for example, Ess et al., 2002). In 2007, the British Psychological Society (BPS) published its guidelines for ethical practice in psychological research on-line in the form of a supplement to its Code of Ethics and Conduct (BPS, 2006). The new BPS guidelines identify and discuss two, key issues for Internet mediated research, namely, levels of identifiability and levels of observation (BPS, 2007). The guidelines state:

"Internet mediated research requires the application of the same controls, checks and balances that apply to good research in traditional settings. It should also involve the same ethical considerations being given to people who are taking part in the research, whether they are simply being observed or are invited to actively engage in experimental tasks or activities...

... While some elements of good practice for ethics in Internet mediated research apply to all, or most, research contexts, the relevance of other aspects must be judged by individual researchers and by ethics committees, with decisions applied as appropriate to the specific research context at hand." (p. 1-2)

The consideration and application of ethical standards to this research are in accordance with the BPS guidance (BPS, 2006; BPS, 2007) and information on the ethical permission obtained for the investigations is given in sections 7.6 and 7.7.

7.5.1. Reflexivity

Transparency – to allow the readers to assess for themselves the researcher's interpretations and conclusions – and reflexivity are both important components of rigour in qualitative research (Smith, 2003). Throughout this thesis, the researcher maintained a reflective journal by using a password protected blogging tool in the university's e-Portfolio system, Pebblepad. Initially, the reflective blog had been started to support reflective practice as a trainee health psychologist. The researcher realised, however, that using a private, electronic blog was equally suitable for supporting researcher reflexivity and it was used for that purpose throughout the quantitative trial and throughout the subsequent, qualitative study for this thesis. Using the electronic blogging tool had a number of advantages over hand written entries in a reflective, project notebook. Pebblepad can not be temporarily mislaid or lost altogether, and it is always accessible to make new entries or to read old ones, given access to any computer with an Internet connection. It offers a permanent, private and confidential record, which can not be viewed by any other person without the writer expressly choosing to arrange to give them access. Privacy and confidentiality, which may be compromised by having a written record on paper, can help to encourage open, honest and self searching reflection.

Each blog posting is stored, dated, in chronological order, in a format that makes it fast and easy to review the trajectories of thoughts, questions, emotional responses and problem solving as they developed in real time. Typically, a fast and unedited account of the working week was entered each Friday afternoon, with additional entries made as and when the researcher was particularly thinking about a topic (for instance, this researcher's paradigm and how to develop on-line relationships with email interviewees) or trying to analyse and resolve practical problems (such as possible ways to overcome recruitment difficulties). There may also be a therapeutic aspect to writing down one's responses to difficulties encountered during the research process – using the privacy of the blog to “let off steam”. For example, frustrations with unexpected problems arising during the preparation for carrying out the CD pilot evaluation were expressed vigorously in the safe, private space of the blog, allowing the researcher then to move on to conduct a potentially problematic, interpersonal relationship in a more balanced, thoughtful and constructive way.

Reviewing the blog entries revealed to this researcher how much detail about the process of carrying out research is quickly lost through forgetting, unless one has a contemporaneous record to which to refer. For example, reviewing some entries made during the recruitment period for the quantitative trial allowed the researcher to recall some of the questions in her mind at that time and subsequently to include them in writing up the research. An accurate, retrospective account of the process of analysing and re-analysing the qualitative data presented below was only possible after consulting the blog entries made at that time. Postings also record how the researcher reflected on the prior assumptions that she was bringing to the qualitative study - including her assumption that a self help package for early, non-specific back pain was likely to be helpful - assumptions she needed to try to hold to one side in “bracketing” for the qualitative data collection and analysis. The researcher has never experienced low back pain and commented in her blog that at least she would not be influenced by her personal experience of the condition. Some excerpts from the reflective blog are given in section 7.7.4.

7.6. Exploring an on-line focus group for an IPA investigation of back pain and self help

The availability of a virtual learning environment (WebCT) at QMU and the potential advantages of on-line research – especially its avoidance of the need for participants to travel, its national, geographical reach and its inexpensiveness - made virtual focus groups an attractive possibility for exploring back pain sufferers' experiences and perceptions of self help. The focus of the research interest in this thesis is early, non-specific low back pain. However, approaching people in the very early stages of back pain to investigate self help seemed unlikely to illuminate relevant processes given the apparent lack of interest in self help among this group as evidenced by the recruitment difficulties for the CD trial (Chapter Six). It was considered it could be more valuable to talk to people with longer experience of living with back pain, who would be able to reflect on their experiences of using self help to manage the condition over time and if and how their perceptions had changed. The researcher approached a national back pain charity, BackCare, to discuss the possibility of publicising an OFG to their members, most of whom are likely to have a more lengthy, personal history of back pain. The charity was supportive of the research idea and suggested that,

before it agreed to help with recruitment to an OFG, the proposed WebCT research site should first be evaluated by three of its local area organisers.

The researcher had discussed the possibility of hosting an OFG on WebCT with the university's VLE administrator. The preliminary discussions covered a range of issues, including potential advantages and disadvantages of using e-learning tools for research purposes. Advantages included the provision of a secure, confidential and safe on-line research environment, with technical support from the e-learning administrator. Potential disadvantages were also raised, such as questions about how a Freedom of Information request would be handled should this arise, given the VLE was in the ownership of a public institution, and restricted accessibility for visually impaired users.

Following receipt of ethical approval for the project from QMU Research Ethics Committee, the administrator created a customised, private research area within WebCT. Icons on the research area's home page, which announced the title of the study and included the university's institutional logo, provided three links (Appendix 10).

The first link opened a page where documents gave details about the back pain research, which included its purpose, details of what participants were being asked to do, institutional contact details and information about who had access to the on-line research area. In addition, it had a Netiquette Guide and a Guide to Using WebCT, both of which had been created by the researcher specifically for the on-line study participants. These documents were duplications of information supplied to participants in advance of the OFG, which were also made available in the on-line research area for easy reference. See Appendix 10.

The second opened a multi-threaded discussion tool, where participants could post their messages as responses both to the researcher's questions and to other participants' posts. Messages posted under the same topic heading are visible to all group members and to the researcher. These messages are automatically organised into "threads" (or on-line "conversations") as they are posted.

The third link opened a survey tool, which could be used to gather feedback about taking part in the WebCT study at the close of the OFG.

The e-learning administrator manually created individual accounts in WebCT for each of the three OFG participants whom BackCare had suggested represent the organisation for the purposes of piloting an OFG for their members. The individuals' account details were emailed directly to the participants by the researcher, giving each of them a password and log-in name to access the OFG. The asynchronous OFG was to be live for a trial period of two weeks, moderated by the researcher. The participants were one woman and two men, all with long experience of back pain.

One of the organisation's evaluators of the WebCT OFG found his participation was hampered by repeated power failures at home following local storms. Two found the demands of living with back pain a barrier to keeping up with a group discussion, even when it was an asynchronous discussion; unpredictable pain flares, tiredness and dealing with the side effects of medication meant there were stretches of time when they felt unable to sit down at their computers. This made it difficult to maintain a flow of "conversation" among the three members of the group, even when individuals were intermittently responding to the group moderator's postings. That additional level of data, generated by interaction between group members, is an important characteristic of focus groups. Without it, the OFG moderator is in effect conducting multiple, semi-structured interviews on-line in the "presence" of other interviewees.

A fortnight after the asynchronous on-line discussion had gone live, the researcher contacted each participant individually for detailed feedback. None had previously used WebCT. Nonetheless, they

reported they had not found it difficult to log on and to navigate through the site, all commenting that the supplied Guide To Using WebCT and Netiquette documents had been helpful and clear.

Although the three OFG members had liked the idea of being part of a discussion group and had found it reasonably straightforward to learn to use WebCT, all had experienced problems during the fortnight's pilot of the OFG. These had interfered with their regular participation in the on-line group. For example, one OFG evaluator wrote towards the end of the first week:

"I am sorry I have been unable to access my computer until today, my back has been so bad I have been in bed for several days. I am feeling a little better now so hopefully I will get back to visiting the site. I also find if I have been working all day I can't access my computer that day. I have to stretch out or I am unable to cope for a couple of days."

Another wrote, in the second week :

"I am sorry about the problem (participating in the group). My back pain flared up and I have had new medication, i.e. Fentanyl patches, and they have made me feel somewhat disinclined to do anything much. I would like to help! I now think email interviewing would be better."

These participants later reported that, when they were able to visit the research site, they did not like to continue the discussion by making more postings of their own until other members of the group had contributed. Hence the reasons for the stalling of the asynchronous discussion were two fold: participants were often unable to use their computers for various reasons, particularly increased pain and tiredness; and participants who would have been able to contribute were "waiting" for others to do so first. The latter may in part reflect the unusually small number (three) of participants in the evaluation OFG and that these participants may also have known one another outside of the on-line discussion forum.

The OFG evaluators suggested in their feedback that an individual approach would be preferable. There was consensus that being interviewed individually by email would remove the pressure on people of feeling they were “holding up” a group discussion whenever they were unable to participate for personal or technical reasons. Email interviewing would preserve the advantages of having time to consider responses and of being able to choose when, and for how long, to sit at the computer, thereby accommodating the vagaries of living with back pain. Accordingly, it was agreed to carry out semi-structured interviews by email to investigate BackCare members’ perceptions of self help, rather than proceeding with an OFG hosted on WebCT. This adjustment would entail the loss of potential OFG data from interactions between group members, however, individual interviewing was also an appropriate research method for investigating the topic and one well suited to IPA methodology.

7.7. An IPA investigation of back pain sufferers' experiences and perceptions of self help for pain management

This study was granted ethical approval by Queen Margaret University's Research Ethics Committee.

7.7.1. Overview

Nine people with persistent, non-specific low back pain were interviewed by email to explore their experiences and perceptions of using self help for managing back pain. An IPA analysis revealed four, major themes: taking control, social comparisons, ongoing learning and “with hindsight”. The findings suggest that turning to self help strategies for managing back pain may be a developmental process over time, related to the variable course of back pain symptoms.

7.7.2. Introduction

The experience of living with chronic back pain has been explored previously in qualitative studies, notably in IPA studies by Smith and colleagues (for example, Smith et al., 1997; Osborn & Smith, 1998; Smith & Osborn, 2007). Such studies have illuminated how persistent, debilitating back pain

can have a powerfully negative impact on individuals' quality of life and psychological well being. People with persistent, non-specific pain may struggle with uncertainty about what is causing the sensation of pain and what it might signify, feel unable to establish legitimacy and direct anger towards themselves and others, including towards health professionals. Sufferers may perceive their situation to be shameful and stigmatising and withdraw from social contact. Interviewees in the study by Smith & Osborn (2007), for example, described the powerful, negative impact of persistent pain on their sense of who they were. The authors reported that this "assault on the self" was experienced as more distressing at times than the physical sensation of pain by their interviewees. These participants had all stopped working because of their back pain and had recently been referred to a U.K. pain clinic. While the debilitating impact of pain on the sense of self was the primary finding of the IPA study by Smith & Osborn (2007), how that impact was experienced differed between individual participants. In the view of Smith & Osborn (2007):

"Indeed there is the suggestion of the possibility of a developmental process, patients beginning with a fight to retain the positive original self, then beginning to doubt the possibility and finally resigning themselves to a new less desirable self taking over." (p. 523)

Similarly, a narrative study by Walker et al. (1999) highlighted negative processes and outcomes for patients with chronic back pain. Analysis of interview data by Walker and colleagues identified five, major themes: that the pain takes over; a sense of loss; in the system; they don't understand; and coming to terms. The interviewees were patients currently attending a pain management programme at specialist pain clinics in England. All described their feelings of having become trapped inside medical, social security and legal systems and attendant, negative affect, such as powerlessness, helplessness and anger. The authors suggested that the commonality of these patients' feelings of entrapment in different systems supported situational explanations for the negative attitudes often reported in chronic pain patients:

"Frustration with 'the system' was expressed by all of those interviewed, whilst bitterness and anger lurked just beneath the surface. Anger appears to be a salient feature of the chronic pain experience, but one which is frequently repressed." (p. 626-7)

Other work, for instance, Osborn & Smith (1998), has revealed the equivocal nature of social comparisons for persistent back pain patients. Interviewees' uncertainty about their own prognosis could undermine the potential benefits of making downward social comparisons. One participant described how she wondered if she were looking at herself in the future when she saw someone else with more disabling back pain, for example (Osborn & Smith, 1998). The researchers write:

“This comparison with others who were more unfortunate was intended or considered as a strategy for enhancing self-esteem but often turned into a reinforcer of despair.” (p. 71)

No previous investigation has specifically explored back pain sufferers' experiences and perceptions of self help for managing back pain. Further, prior qualitative work has recruited participants who were currently attending or who were about to attend a programme at a pain management clinic in an effort to address difficulties they were experiencing; it may be assumed that previous studies' participants were struggling to cope with living with ongoing pain and its impact on their lives. To this researcher's knowledge, no prior study has investigated the experiences of people living with chronic back pain who are, by and large, coping quite successfully, either following completion of an NHS pain management programme or without ever having any such intervention.

7.7.3. Recruitment

The national back pain charity, BackCare, agreed to support recruitment to the study following discussions about the research with representatives of the charity's organisers and an agreement to pursue data collection by email interviewing, rather than through an OFG. Feedback from an evaluation of using an on-line discussion forum had indicated that individual, email interviews were felt to be more suitable for carrying out research with the charity's members (see section 7.6.). Publicity about the email interview study and an invitation to contact the researcher for more information if interested were circulated to the charity's membership. Potential recruits who subsequently contacted the researcher were emailed or posted a Participant Information Sheet

and a Consent form (Appendix 6). Nine participants were enrolled sequentially after they returned their signed consent forms.

The nine participants formed a reasonably homogeneous, purposive sample (Smith & Osborn, 2003). All were white, British, English speaking and in middle adulthood, with ages ranging from 38 to 61 years. All had endured back pain for more than 10 years. Four of the interviewees had attended back pain management programmes in the past, at different locations in the U.K. None was currently in treatment. Brief descriptions of the participants – with changed names and with identifying, autobiographical details removed to protect anonymity - are presented in section 7.7.5.

7.7.4. Procedures

Methods: The data were collected in 2007 by semi-structured interviews, conducted asynchronously by email. Most interviews were completed within a period of four to five weeks. Participants were asked to write as much as they wished in response to the interview questions (Appendix 11). Printouts of the emails formed the raw data for analysis. In an attempt to create and maintain rapport and to encourage extensive responses by email, the researcher told each participant something about her own background and interest in the research topic, followed by an initial email to start off their study participation, saying:

“To start with, it would be helpful to know a little bit about who you are, what you do and the story of your back pain.”

Although conceived of as an “ice breaker”, typically this message elicited long, detailed stories with a wealth of detail about the interviewees’ past and present circumstances, perceptions of the roles of other people, references to family members, and more. Much of the rich interview data about participants' experiences emerged in the responses to this initial communication.

In addition, the researcher used basic counselling skills of reflecting and paraphrasing throughout the email interviews. The researcher is an experienced, telephone counsellor for a local charity.

Reflecting back the affect that a participant had conveyed by email to the researcher was thought to help to build up an empathetic alliance and to establish rapport. Paraphrasing – returning a summary of what the researcher had understood the participant to be saying in the previous response before moving on to the next question – served a number of purposes. Importantly, it allowed the interviewees to check that their last email had not been misinterpreted and to clarify or expand their original response if wished. It also allowed the researcher to demonstrate that she was engaged with their accounts and attentive to their responses, and it offered a smooth lead into any request for clarification or probes to elicit further data from the interviewee if these were deemed desirable.

Lastly, the researcher tried, whenever appropriate, to pick up on parts of the emailed texts that did not relate to the interview topic and to use these to “chat” before signing off each time. For example, the researcher variously signed off emails to participants by commiserating with an unwanted rugby match result, offering congratulations for a grandchild’s achievement and comparing notes about local weather conditions.

Taken together, these strategies seemed to be effective for eliciting satisfactory qualitative data, despite the lack of face to face cues in email interviewing. One participant persisted in providing brief, although focused, responses. Other interviewees’ responses were often longer and reflective. Participants commented at the close of the study that they had enjoyed being interviewed by email and some commented that they had also found the process helpful: considering their interview responses had served to clarify their own thoughts and feelings about how they managed living with back pain. At the end of the interviews, participants expressed interest in hearing more about the research when it was finished. The researcher confirmed that she would provide a written report of the findings to BackCare, from where it would be freely available to all participants.

Analysis: The data were analysed using IPA. The analysis procedures were closely based on those described by Smith et al. (1999). In the first instance, all the completed interviews were repeatedly read over until the researcher felt thoroughly familiar with all of the accounts. This built

on a degree of familiarity already gained from the exchange of emails, including sending written summaries of interviewees' responses throughout each interview. The content of one interview seemed to be a rich and in many respects fairly typical example of the interviewees' data and this participant's account was chosen for the initial analysis. Going through this text again, the researcher made brief notes in the left hand margin, capturing the researcher's impressions of what the interviewee was saying, associations and first attempts at short summaries of the data. These notes then served to create a preliminary list of concepts that were present in the data. These concepts were noted in the form of a list of key phrases down the right hand side of the pages. At this stage, all of the interview contents were being included, without selection by the researcher.

The preliminary list of concepts from the first interview was:

- limitations of NHS help for low back pain
- comparisons with other health care systems
- suggestions for improvement
- managing self image
- self efficacy and control
- making narrative sense of uncertainty
- social support from people with low back pain
- social support from others
- perception of norms
- problem focus coping

- emotion focus coping
- coping appraisal
- barriers to self help
- low back pain as a negative entity
- low back pain as a neutral/positive entity
- social comparison with others with low back pain
- meanings of low back pain terms

Subsequently, each of the remaining, eight interviews was read again and instances of the preliminary, identified themes were highlighted and noted in the right hand margins, along with annotation of any data that suggested new concepts that had not previously been found. At the end of this process, the key words that had been extracted from all nine interviews were written on a separate sheet of paper and considered together. At this stage, the researcher was trying to see any relationships and to organise the preliminary list of key phrases into clusters of connected ideas, or themes.

The researcher then returned to the emails to check that each of the identified, preliminary themes could be supported by verbatim text from interviewees. One preliminary theme, arising from an interview question on what participants understood by the terms, “acute”, “sub acute” and “chronic” in back pain was now dropped because it yielded short, factual (and largely well informed) responses based on temporal categorisation. Similarly, other preliminary ideas for themes that had proven to be poorly represented in the body of interview data, in terms of data richness, were now discarded, specifically, the preliminary themes of comparisons with other health care systems and of making sense of uncertainty were dropped at this stage. Selecting themes for the richness of their representation in the raw data is concordant with the role of an IPA analyst in the research process being an interactive and dynamic one (Brocki & Wearden, 2006).

The themes that now remained were clustered as follows:

- NHS

limitations of NHS help for low back pain

suggestions for improvements

- perceptions of self

self image

control/self efficacy

- social factors

support from people with low back pain

support from others

social comparisons

- coping strategies

problem focus

emotion focus

appraisal

barriers

- low back pain as an entity

Next, the researcher created a Word document in which these clusters (NHS, perceptions of self, social factors, coping strategies and pain as an entity) were displayed as key themes and sub themes, with references to the page numbers and paragraph of the email printouts and examples of supporting quotations from interviewees (Appendix 12). At this point, the researcher spent some time reflecting on this document and the story she could tell from it. It was recorded in her reflective, research blog (see section 7.5.) that she had an uncomfortable feeling that some essential element of the interviewees' phenomenological narratives had been lost. After wrestling with feelings of dissatisfaction with the first analysis for some time and trying to understand "what's gone wrong?", the researcher wrote in her blog: "Aha! I think I've got it!" She believed that she had abandoned "bracketing" prematurely and had moved too quickly to fitting the participants' data into her own, preconceived categories derived from social cognitive psychology. Hence the interviewees' phenomenological narratives had been overwritten by her own interpretative perspective. The researcher returned to the IPA literature to seek guidance. The dilemma seemed to relate to an assertion by Smith (1999) that:

"...from an idiographic perspective, it is important to find levels of analysis which enable us to see patterns across case studies while still recognising the particularities of the individual lives from which those patterns emerge." (p. 424)

Further, writing later, Smith argues that although an IPA researcher should be informed by the psychological literature, the data analysis should not be directed by any specific, prior theoretical position (Smith, 2004). A blog entry, posted by the researcher during the stage of identifying preliminary themes from the first interview, read:

"It all seems to be relating rather nicely to Leventhal et al.'s 1997 cognitive model of illness perceptions, i.e. interpretation, coping & appraisal. Also to coping skills lit., especially problem focus (seeks information and support, takes action) and emotion focus. Maybe Moos & Shaefer? Oh, and to Fishbein et al.! Hurrah! - at least, to three of the four broad classes of variables, i.e. relevant referents; barriers and facilitators (environmental constraints, self-efficacy/control); and perceived personal characteristics (self image)."

Later, the researcher's reflective blog records some internal debate about the advantage (notably, time considerations) of proceeding with the initial analysis despite feeling dissatisfied with it and the advantages of returning to re-analyse the data in light of her new understanding. On ethical grounds, in terms of doing justice to her participants and of producing the best research of which she was capable, the researcher clearly recognised that a second, less theoretically driven attempt at analysis was required.

At this juncture, the researcher returned to the original printouts, with the deliberate intention of remaining open minded about how those ideas extracted from the data and noted in the left hand margins should be understood and labelled in the right hand margins. It was felt that the research would be more transparent, and therefore more rigorous, if the analysis were to be presented in such a way that the phenomenological narratives remained the focus in the presentation of the findings, with the researcher only then abandoning bracketing to apply her social cognitive perspective in a subsequent, interpretative discussion of the narrative themes.

The second IPA analysis, repeating the same procedures, described above, on the same interview data, now elicited four, main, shared themes. The first three emerged from the interviewees' accounts whereas the fourth, "with hindsight", reflected the structure of the interview, specifically the question: Knowing what you do now, what are your views on the ways in which early back pain is handled? The interview schedule is available in Appendix 11. The four themes were:

- taking control
- social comparisons
- ongoing learning
- with hindsight

It was noted in the researcher's reflective blog that the four themes seemed very different from the initial list of themes; they captured the same insights from the same narratives yet were clustered under headings that closely corresponded to the interviewees' stories, rather than to prior, theoretical understandings held by the researcher. A colleague engaged in IPA research reviewed the revised main themes to confirm that they were represented in the interviewees' text. The aim of consulting colleagues in this way was not to achieve an agreed or "objective" interpretation of the extracted themes but to help ensure that the researcher's own, subjective account was a trustworthy and credible one in that it was grounded in the research data (Osborn & Smith, 1998). This second and final, analytic account is supported by verbatim quotes from the interviewees. According to Brocki & Wearden (2006), providing direct quotes enables readers to evaluate the researcher's interpretations and is central to the presentation of qualitative research findings.

The reporting of the IPA study is organised as follows: In the findings section (7.7.5), a phenomenological approach informs an account of narratives obtained from people who were interviewed by email about their personal experiences of back pain, with attention being paid to their reported, subjective experiences of embodiment, self identity, relationships and temporal references. This section opens with a description of the circumstances of one interviewee, around whose narrative the thematic findings are structured. The findings are organised into four, main themes, which were arrived at without the imposition of any prior, theoretical framework from any particular psychological discipline. Each of these four themes – taking control, social comparisons, ongoing learning and "with hindsight" – is presented in turn, drawing on a variety of interviewees' accounts and using direct quotations to illustrate both similar and different aspects of that theme. Throughout, the reader is able to distinguish between the researcher's commentary and the interviewees' verbatim, narrative accounts. The focus of the investigation is self help for back pain and interviewees' accounts of their experiences with regard to using – or not using – self help are integrated throughout the main themes. This integration reflects the structure of the narratives as they were told by the interviewees.

The presentation of the findings is followed by a discussion section (7.7.6), in which the researcher offers an interpretation of the narratives through the hermeneutic lens of social cognitive psychology, which reflects the researcher's own training and professional knowledge. Similarities and differences between the main themes reported here and those found in prior, qualitative work on chronic back pain are considered. Finally, the conclusions drawn from the qualitative study are presented in section 7.7.7.

7.7.5. Findings

The findings section begins with background information on the participant whose interview was analysed first and from whose data the scaffolding for the final, full analysis of themes was derived. This is to set out the context for her story so that the reader may have a feel for who is talking. Very brief information on the other interviewees' back pain histories is also supplied at the close of the section (Box 5). Care has been taken to ensure individuals can not be identified from this information. Personal, background information about interviewees would not normally be presented in a journal article, where word count limits constrain how full an account may be given, however, the greater flexibility with regard to report length in a thesis permits greater transparency for the reader about the analytic procedures followed and about whose subjective accounts are being analysed, as well as permitting the presentation of more extensive examples of what was actually said by interviewees.

Shona has children and grandchildren and works part time. Shona describes having had low back pain on and off since the early 1990s, usually starting following strenuous activities, such as gardening, decorating or heavy lifting. She said the pain normally eased off after stopping whichever activity had brought it on. She attributed this at the time to a general lack of suppleness that came with getting a bit older. One morning, she woke up with severe low back pain:

“I just could not get out of bed, the pain was so acute. I literally had to almost crawl on all fours to get to the bathroom, holding on to walls and doors, and I had to call out my GP as there was no way I could get to the surgery.” (Sh/1.1)

The severe episode gradually resolved over a period of months but, since that time, she has experienced stiffness in the mornings and a dull, lower back ache. Shona describes her current low back pain as “sporadic”:

“(It) lets me know it's there with a constant ache for a time, with periods with a little, residual discomfort, but I also get occasional more severe flare ups which can be very uncomfortable for a few days until they settle down.” (Sh/1.1)

Shona's large repertoire of coping strategies for her back pain has included visiting a chiropractor and an osteopath, neither of whom she found helpful, trying the Alexander Technique and Pilates and sometimes using complementary health practitioners. She says she has benefited most from private physiotherapy sessions. Currently, she reports using seat supports, eating well and taking food supplements, doing a daily exercise routine recommended by a physiotherapist in addition to other physical activities, information seeking and seeking social support. She is an active member of BackCare. In addition, she takes painkillers “from time to time, just when needed”.

Shona's narrative account of learning to live with back pain is a story of trial and error, persistence and the recognition of diversity among back pain sufferers. As such it seems an exemplar of the narratives of these interviewees who are generally coping well with living with chronic back pain.

Taking control: Shona talks about low back pain as if it were an opponent over which she has actively chosen to exert control, referring to her need to avoid low back pain “attacks” and not allowing herself to be “dominated” by low back pain. Low back pain is at once an integral part of her daily life and spoken of as a separate entity with which she consciously engages, reflecting the shift from subjective body to objective body described by Toombs (1993). Shona writes:

“I feel it is important not to give in to pain.” (Sh/5.1)

Her relationship with this entity of pain is not exclusively negative, however. Shona suggests that, with hindsight, she can also find some positive consequences of its arrival; she now leads a healthier, more active life. She reflects:

“In retrospect, my bad back episode was a warning to me to change my lifestyle.”
(Sh/5.1)

Taking and keeping control emerges as an important theme in Shona's narrative, with an explicit awareness of the negative consequences she perceives for herself if she fails to achieve this. These perceived consequences are psychological as well as physical, indicating that in Shona's world view, mental well being and physical well being are interconnected.

“From a psychological point of view, it is much more healthy for me to feel in some measure of control of the problem, rather than just give in and think nothing can be done. ... It helps prevent a downward spiral of depression setting in.” (Sh/2.2)

Further, Shona appears motivated to “take charge” of her own situation by the perceived consequences for other, important people in her life if she does not.

“If I had not taken action myself, I could have just sunk into a depressed state, which would have affected my whole life, and that of friends, family and colleagues.” (Sh/2.2)

Shona's pursuit of control encompasses acceptance of the ongoing presence of back pain in her life and an acceptance that she has personal responsibility for its management, with support from a range of others. The importance of her social world in which she tries to minimise the effects of her back pain is paralleled by the importance to her of a social world in which the reality of living with back pain is central, namely, her membership of BackCare. Shona emphasises how much she has learned from joining her local branch of the national back pain charity, speaking of gaining valuable information from talking “with others with the same problem” and taking part in social activities, such as a weekly, warm water swimming session.

"I would say that joining the local branch of BackCare was definitely the biggest influence on me. Getting involved on the local branch committee and helping run their activities has changed my life and outlook." (Sh/1.1)

Other interviewees express the importance of taking control in different terms. Tom describes it as taking overall responsibility for how he lives his own life, making allowances for his back pain by making changes to what he does or how he does it, when necessary, so that "life goes on":

"You have to understand that it's down to yourself to sort out living with back pain, as far as it can be sorted out. It's down to you at the end of the day." (T/2.2)

For Pete, it entails being assertive at work:

"My job certainly involves some heavy lifting duties but not excessively so, and I believe I am responsible for what work I agree to do." (P/2.2.)

Ginny's narrative reveals a more complex attitude to maintaining control, in which "letting go" also has a positive role for her. She describes an ongoing struggle between a controlled self and a rebellious self:

"Somehow, after a while, an irresistible sense of rebellion kicks in and all good resolutions disappear! After a spell of disappointing progress, a 'what the hell, it's only pain' approach kicks in, which means just going and doing what you really want to do. Sometimes this can work but, obviously, sometimes it leads to setbacks. Still, worth it from time to time, just for the sake of morale!" (G/2.2.)

Ginny says she has "learnt to listen to my body", nonetheless, she describes choosing to move between acting in her subjective body and attending to her objective body for "the sake of morale". Exercising control is manifested in different ways in Ginny's account, by choosing to exert self control, choosing to rebel on occasions and by reclaiming some autonomy in decision making from the health professionals:

"Initially, I would follow the medical and physio advice being given to me by the letter, in

the hope that it would prove to be the definitive solution. Now I know that it is only a question of planning the wisest management programme for the current situation and, to a certain extent, I am the best person to judge things like the intensity and duration of exercise.” (G/10.2)

Ginny's use of tenses, from “I would...” to “Now I know...”, traces the trajectory she has followed. In common with other interviewees here, she seems to have travelled a path to reach an acceptance that she will not find a “definitive solution” to her back problems. Now, she adopts a more flexible range of responses to deal with variable circumstances.

A further facet of control revealed in some interviewees' accounts is the exercise of self control in the public arena, where participants are aware of managing the self that they present to others. For example, Ruth describes feeling it necessary to manage her self presentation in her dealings with a GP:

“I had the feeling that the GP thought I was exaggerating my problem and was probably an anxious type of person. As the pain did indeed make me anxious, I tried to only see my GP when I felt able to hold a calm discussion.” (R/2.1)

For Valerie, it is a matter of exercising self control in public – by not complaining - to maintain the good social relationships that are important to her:

“For me, one of the most difficult things about back pain is how it affects the rest of my life. I like to be out and about, to have a social life. Back pain is very isolating. I really have had to work hard to keep in touch – but be careful not to moan.” (V/2.1.)

Social comparisons: Talking to other people who have back pain allows Shona to garner information and also to make social comparisons. She describes herself as being relatively fortunate because the intensity of her back pain fluctuates.

“I feel lucky that I do not suffer from back pain all the time. I know that others do have a much more difficult problem to deal with.” (Sh/6.1)

Shona's use of social comparison is complex. On the one hand, her downward social comparison allows her to feel "lucky". On the other hand, she uses social comparisons to foster a sense of belonging to a body of diverse back pain sufferers, not to separate herself from strata within it. She combines being "lucky" with her self efficacy beliefs for her successful management of her own pain and thus does not negatively judge back pain sufferers who cope less successfully. She repeatedly stresses diversity:

"Most of what I've said is what works for me. All I would say is that people troubled by back pain are very different in the severity of their condition, and their personal attitudes to the condition." (Sh/6.1)

And:

"It is a very difficult condition to generalise about and, as I have done, most people seem to have to go through a range of practitioners and products until they find what gives them some means of getting on with their lives, without being dominated by back pain." (Sh/6.1)

Tom also refers to feeling supported and informed by talking to other people with similar problems and seems to use social comparison to normalise his own experience; he is one among many.

"It's others with back trouble who know what you're talking about. Having said that, it's always different. I know so many folk, young and old, troubled by back problems of one kind or another. You could say it was a national epidemic!" (T/3.1)

He returns to his experience of the diversity among back pain sufferers later in the interview:

"We are not all the same. It could be something to do with different injuries at the start or different tolerance and folk have different things going on in their lives as well. That makes a difference." (T/6.1)

Another interviewee refers to social comparison in the family sphere. Here, the participant is describing her birth family's attitude towards back pain and seeking to establish a different identity for herself from the "invalid" identity of her mother, who also had back pain:

“Both my parents had back problems. My mother had a bad back and lived in a corset from when I was about five. And in my family during my childhood, when things got difficult or my dad overworked, their backs 'went'. So it was quite acceptable to have a bad back in our family. I thought that I might be like my mother, who was really quite an invalid for a lot of the time. I didn't want to be like her.” (V/6.2)

Again, it is evident this interviewee has a biopsychosocial understanding of pain, an observation that echoes Tom's previous comment that what else is “going on” in people's lives influences how they cope with back pain.

Ongoing learning: Shona's narrative reveals the primary importance of continual learning throughout her back pain experiences – learning about others with back pain, learning about her own back pain and what does and does not help her to manage it, and learning about herself, including learning to overcome challenges to her self identity by accommodating or assimilating changes arising from having back pain. The image of self present in Shona's narrative is that of a healthy and active person, with continuity from the past into the present shown in her choice of words: “I have always been...” She supports this perception of herself with the unsolicited presentation of her many activities, interests and hobbies:

“I have always been an active person and enjoy cycling, swimming, walking, gardening, various crafts (....), cooking, learning languages, cultural events, reading, current affairs, travel and socialising with family and friends.” (Sh/2.1)

The initial, debilitating episode of severe back pain posed a serious challenge to this sense of self:

“For about two to three weeks, I was walking about almost doubled up and felt unable to straighten up. I could not drive. It was really depressing, even for that shortish time. I felt more like age 80 than 50, which I was at the time.” (Sh/2.1)

Nonetheless, Shona goes on to maintain a coherent sense of self by assimilating that experience and subsequent experiences, which include an unrelated, long standing medical condition and surgery, into her “healthy” self identity, stating in the present tense:

“I am generally very healthy and have had no major illnesses.” (Sh/2.1)

Similarly, Ruth states:

“I was physically fit, and still am.” (R/1.3)

That there is an implied comparison between her pre back pain self and her current self in the use of the past tense followed by the present tense suggests the continuity of a coherent self may perhaps be less secure in this instance. Similarly, Tom talks in the past tense to describe himself before he first had back pain and moves on to “I would say” to describe his present self, before projecting into a future in which he might one day become a grandfather:

“I'd always been a fit bloke before... I would say I was still a fit and active person... You need to keep yourself fit with kids. I want to be fit enough to play football with my grandsons one day!” (T/2.1)

Ruth writes that people do not realise how long it takes to learn how to handle living with back pain and how much there is to learn. Interviewees state that they are “still learning”. The long lists of self help strategies (some of which have been tried and abandoned and some of which are maintained) that are recounted in these stories suggest the interviewees share an ongoing willingness to try different things – and to keep trying. Shona has developed views on what should ideally be available to new, NHS back pain patients. She compares these with a recollection of her own early experience of NHS care for back pain, which she describes as “very limited” at a time when she knew “virtually nothing” about back problems and wondered if she would be permanently in that bad state. In common with other participants, it was her perception of the limitations of NHS care for back pain that led Shona to look for help outside of it:

“I realised that a lot of help and support was available and that most of this was outside the conventional NHS treatment. Certainly I did not get much information or help from my GP, apart from an x-ray, about four physiotherapy sessions, a lower back steroid injection, and advice to do the Mackenzie exercises and take anti-inflammatories and painkillers when needed.” (Sh/3.1)

There is not evidence of anger or personal recrimination in Shona's narrative, indeed, she describes her own GP as “sympathetic” and “knowledgeable”. Rather, Shona, like other interviewees, ascribes the limitations to failures at an organisational level, including perceived failures in doctors' training and inadequate resources for NHS physiotherapy. Similarly, Ruth writes of learning from her experimentation with different approaches to pain management only after a period during which she had many NHS consultations, at that time, still in the hope of a “cure”.

Ruth says:

“I began asking whether there was nothing much they could do and whether I needed to accept that I could always have back pain. This usually made them quite flustered and they would tell me not to be so pessimistic – and to try a different painkiller. It was a considerable relief when one GP did finally agree that there was not much he could do. I felt I was being treated with honesty at last.” (R/5.5)

She recounts:

“I was next persuaded to go to a chiropractor by a colleague who knew someone who had been helped after post-childbirth pain. It did not help but I was impressed by her knowledge and skill and I came away with my first, small insight about pacing myself. So, I was ready to try something else and several, sensible friends were encouraging me to try Alexander Technique. Again, I was motivated by the fact that it began producing small improvements almost straight away. The Alexander teacher emphasised the need to keep practising and I could see the sense of that. So physiotherapy exercises, maintaining fitness in general and Alexander Technique became my self help strategy.” (R/4.3)

Pete's preferred self help strategy is to lie on a wooden, back support cradle. He too describes a number of attempts to help himself before finding something that: “... although it is no cure, it keeps it at bay”:

“Initially, I ordered a book from Amazon called the Back Pain Book or some such title, which gave me a few exercises, which I must say were initially quite helpful, to the point where I could walk again. But the pain persisted. I eventually paid to see a chiropractor.

She put me through additional pain but I certainly felt 'cured' afterwards – until I got home, when the pain would start building up again. I saw an ad in a Sunday paper for Flexibak – a wooden device for re-setting the spine by gentle pressure. I bought it, somewhat sceptically but also somewhat desperately. I felt great after the first session of lying on this thing, and waited for the pain to return, which it did. But I persisted in using the contraption for twenty minutes, twice a day. Each day I felt better.” (P/4.4)

Anne talks about a repetitive cycle of visiting doctors, taking painkillers, perceiving she was expected simply to live with the pain, waiting, then returning to visit a doctor again before she began to embark on alternative approaches to try to help herself. Anne, who visits a chiropractor whom she describes as being her main support currently, writes:

“Try everything offered. Yes, go to a doctor – it might be something they can help with – if you are lucky and get the right doctor. Ice packs or heat pads? Physio might be the answer. It is trial and error. Simply try a painkiller, see what effect that has, or try a TENS machine (which I bought in the chemist for £9.99, recommended by a cousin). Try exercise. In other words, you muddle along the best way possible! My views on self help have changed. I am now convinced that there is no other way but self help.” (A/2.2)

Mary similarly reports trying many different types of self help over the years. Now she focuses on employing the information and support she gets from BackCare and on using relaxation tapes. Mary describes looking for help outside the NHS after initially being prescribed painkillers and being told to rest by her GP, although at the time she had two, young children to look after. She recollects:

“Thinking back to that time, I think my GP actually said that maybe some kind of alternative help would be good. Other than my family, there was little or no help available to me that I knew of then. Indeed, I felt totally isolated.” (M/1.1)

Memories of feeling “isolated”, of “bewilderment” and of being “frightened” when they were initially trying to resolve their back pain problems within the NHS are recounted in several interviewees' tales. Their lack of knowledge at that time about where else to turn for information and an ignorance then about a range of different kinds self help strategies, private practitioners and products that might be tried are picked up in Ruth's story, who comments:

“I would want to discourage thinking they (GPs) had to personally respond to the needs

of patients. I know some kind and conscientious GPs do try to provide the support their patients need and it isn't appropriate in the time they have to offer. Rather they should know what help, support and advice are available, and see it as an essential part of their role to put the patient in touch with these resources." (R/1.1)

Some interviewees relate experiences of early consultations with doctors who were perceived as uninterested and not to understand the profound impact back pain was having on their lives, as well as communication misunderstandings between doctor and patient. Ruth says she has had very good experiences of the medical profession, however:

"I was unprepared for the very different treatment I received as a back pain sufferer. ... I would be told I did not need an operation, that the problem was not 'serious' and that I should try a different type of painkiller. I really felt that the GPs did not appreciate the problem and the extent to which it was affecting my life ... I would go back with new information ... I expected them to be interested and to be able to draw some worthwhile conclusions from the new information. Of course they didn't." (R/1.1)

John says he turned to self help because of the:

"...lack of interest from health professionals, even though I was employed by the NHS myself. I was being given conflicting advice about the best way to cope with my situation and improve my physical strength." (J/1.1)

Tom relates the story of his interpretation of advice from his GP to "get active". Tom acted on this initial, GP advice enthusiastically. However, the advice does not appear to have been accompanied by any guidance on pacing activities, leading to a marked deterioration in Tom's back pain for a while. He recounts:

"My plan was to do some serious training in the gym and get fit again that way. It didn't work. It was too much. Ended up far worse than when I started. I've learnt you have to keep your exercise at a sensible level, not go all out for it, thinking that'll cure you. You are told you need to get active again and that's right up to a point but they should be warning you too not to make matters worse." (T/4.3)

These interviewees differ in an array of details but share a common narrative of moving from looking for a "cure" from the medical establishment to seeking alternative ways to manage living

with their pain. Ending the hunt for a biomedical “definitive solution” is not the conclusion for these interviewees, however. Rather, it is a turning point from which there follows a new, often long, learning journey for the individuals, during which the principal elements of self help experimentation and persistence are summed up in Anne's comment:

“It is trial and error.” (A/2.2)

As Tom remarks:

“There is no magic cure for back pain. If there was and I knew it, you'd be interviewing a millionaire!” (T/4.1)

The narratives presented here may be considered success stories; all of the interviewees variously report now being actively engaged with their communities, families, with work and with hobbies, despite chronic back pain. These have not been unproblematic, learning journeys for the narrators, however. The accounts reveal that participants have had to “work hard” to maintain good social relationships, to continue to shoulder work and domestic responsibilities and to pursue recreational interests and leisure activities that they can enjoy despite living with ongoing, often variable, pain. Some interviewees continue to wrestle with anxiety and with tensions between knowing now what they “should” do and implementing intentions. This often appears to relate at another level to their management of the sense of self. Ginny, for example, acknowledges her frustration at some discrepancy between who she “is” and what she is currently able to do:

“I am a keen sports person and am hugely frustrated by the number of activities I have been forced to give up.” (G/2.1)

Ruth uses the past tense to describe her difficulty with pacing activities to avoid pain flare ups yet gives an account of ongoing struggles with this aspect of self management, initially suggesting advancing years as an explanation for her most recent, increased pain before then also acknowledging the possible role of her breaching previously learned boundaries. She is able to

analyse past “miscalculations” and their consequences yet remains vulnerable to feeling she “ought” to be able to do things, particularly for other people.

“You sometimes get away with things better than you anticipate and there are always convincing reasons for doing it again. However, I spent so much of last year recovering from flare ups that I ended up feeling quite depressed and that my pain was controlling me again, rather than me being able to control it. So, this year I am turning over a new leaf. I am not good at saying 'no' to things I want to do and feel I ought to do, but it is going quite well so far.” (R/1.3)

Valerie speaks of self blame framed in the past tense but slips into the present tense as she elaborates, perhaps suggesting her old feelings of guilt have not entirely been laid to rest:

“I felt quite guilty and cross with myself for quite a long time – some of my episodes of back pain are the result of doing silly things, like cutting the new lawn with scissors, lifting a microwave. Whoops.” (V/2.2)

It is evident too there is still residual anxiety about the future for Valerie, who says:

“I have accepted now that nothing awful is going to happen and that I'm going to have bad times and good times. On the whole, I don't worry so much now that something nasty is going to happen.” (V/2.1)

Valerie is able to use acquiring the label of “chronic” back pain as a buffer against the uncertainty of the future to some extent, while acknowledging that this may be rather unusual:

“I know it sounds weird but to me it is a relief that my back pain is now termed 'chronic' because to me it doesn't mean 'likely to develop into something nastier'. I think of chronic as ongoing and something you can come to terms with. You learn to live your life around it. Obviously, it would much nicer if it had gone away altogether.” (V/2.1)

Finally, these interviewees allude to the financial costs of pursuing “trial and error” strategies to try to help themselves to cope with back pain. The researcher did not attempt to impose any definition of “self help” on study participants, whose responses showed that self help was understood by them to include a very wide range of coping strategies, from pacing their own activities to visiting

private health practitioners to utilising social support. Finding and using available social resources emerges as an important aspect of self help, particularly for these interviewees, from family members, good friends, both with and without back pain, and from social contacts made through BackCare. Such support is free. However, participants speak about the expense of buying products and visiting private therapists. When a product or therapist turns out to be unhelpful to them, it does not seem money well spent, while other interviewees refer to the difficulties of finding ongoing funding for those strategies they do find helpful.

Pete chose not to use the NHS at all. He explains:

“I didn't go to an NHS doctor because I didn't want to be given drugs or sent for surgery: this was my perception of doctors at the time. I still think doctors are too keen to prescribe drugs. Back pain seems to be the reserve/domain of the alternative therapist or chiropractor. Looking back, I wouldn't have spent more than £100 on a chiropractor! Sorry to sound flippant but I do have the feeling that no-one can really cure pain.” (P/1.1)

Other interviewees write:

“Unfortunately, some type of self help programme usually means using private physiotherapists and other complementary health practitioners and buying items of equipment. ... This can be very difficult on a limited budget.” (Sh/4.4)

“In really bad times, my visits (to a private practitioner) can be twice a week. Expensive!!” (A/5.1)

“For people who cannot afford private medicine, it's even worse. In my job now I see a lot of people who have lost their jobs, got into frightening debt, even lost their house because their back problem isn't sorted out quickly. And then they get depressed and isolated.” (V/4.4)

With hindsight: Interviewees were asked about their views on how early back pain should be handled, given all that they now know. The following extracts were in response to that question. Shona describes what she now sees as a need for much earlier intervention services for back pain patients and advocates ongoing access to self referral, support services run by the NHS, combined

with GP training in giving back pain advice and faster access for patients to longer NHS physiotherapy treatments. Shona states:

“The perception today is anyone with back pain should just carry on as normal, despite the pain. This is not possible.” (Sh/3.3)

“One change I would make in the way early back pain is first handled in the NHS is for doctors to receive more training about how to advise their patients with back pain. Many GPs seem to have little understanding of back pain and how it should best be treated and just send you away with a prescription for painkillers and you 'just have to live with it'.”(Sh/1.3)

Ruth also suggests benefits from earlier interventions being made available, she suggests, at existing pain clinics, where learning pain management skills could be offered at the start of back pain problems. Simultaneously, she acknowledges that it may be hard for people with early back pain to recognise that they might have a “problem” in the initial stages. She indicates health professionals may have a role in helping people to accept they have a problem. She says:

“I do ask myself whether I would have been much better off if I had been able to take part in a pain management programme right at the beginning. At the beginning it is difficult to accept you have a problem ... I feel it would have been easier to accept in a supported environment where professionals were willing to spend time explaining ... I would like pain management programmes to offer a preliminary module for early pain sufferers. It would need to focus on helping the healing progress, especially learning how not to keep aggravating the problem.” (R/1.3)

According to Valerie, with hindsight, time is of the essence:

“I feel so strongly that so much pain could be avoided, if appropriate treatment was available when needed from the beginning, if we had ergonomic chairs and beds, if people were given proper training to lift and time to do their job.” (V/1.3)

Ginny suggests the immediate referral of new back pain patients to a NHS physiotherapist could be valuable and cost effective. Like others, Ginny emphasises what she now sees as a need for early and ongoing access to support and education:

“Follow up sessions – perhaps monthly – could help the back pain sufferer to adapt their postural habits and activity lifestyles effectively at an early stage and help to prevent the condition becoming chronic. Again, this might turn out to be money well spent.” (G/1.2)

This ideal with hindsight contrasts with her own experience, about which she writes:

“Always, the courses of treatment and prescribing were of a short duration and I would be 'signed off' until the next episode. In retrospect, an ongoing watching brief could have been of great benefit – both emotionally and physically.” (G/1.1)

John, one of four interviewees here who had attended a NHS pain management programme, comments:

“Thinking about the way early back pain is handled in the NHS, what is missing is expert assessment, advice and intervention from the beginning, with a range of facilities for careful monitoring, evaluation of progress and rehabilitation ... We need competent NHS practitioners who can assess each person's situation and recommend a range of options for consideration. No one strategy can be applied to all.” (J/3.3)

These excerpts demonstrate a retrospective recognition by interviewees that immediate and ongoing access to professional support and advice, with health professionals directing them towards self help and “a range of options”, could have been helpful to them. It poses the question, however, of how useful such early intervention would be perceived to be by people first experiencing back pain, to whom a “problem” that requires any active management may not yet be evident. These participants became highly motivated to engage with self help strategies to manage living with back pain; they did not start that way. It can only be speculated whether earlier, active self management - and improved outcomes - would have resulted for these interviewees had they initially been directed to a range of resources and encouraged to try them by a GP or other health professional, as with hindsight they now wish.

Participants' back pain stories are summarised in Box 5.

Box 5. Participants' back pain stories.

- John describes his back pain as starting as serial, acute episodes but with residual pain from each attack building up over a period of seven years until the pain became continuous. He describes his current back pain as chronic, and he has taken early retirement due to back pain, although he is active in his community. John has attended a Back Pain Clinic.
- Mary describes a busy and active life, despite chronic pain that developed over time after an initial, acute low back pain episode following injury failed to resolve. She can still be troubled by pain flares that necessitate taking some days' rest to recover. Mary has attended a Back Pain Clinic.
- Valerie was first troubled by back pain following childbirth. Episodes of back pain continued, eventually leading to long periods off work and surgery. Further sick leave followed, until she was retired on grounds of ill health, against her wishes ("the worst time"). Now, Valerie has returned to part time employment and describes being active in her community and having several hobbies. Valerie has attended a Back Pain Clinic.

Box continues...

Box 5 continued. Participants' back pain stories.

- Ruth gave up full time, paid work when the sitting and travelling involved in her job became too much of a problem due to back pain. She has since worked part time and does voluntary work. She describes her current back pain as chronic pain that is usually “a dull aching”, although last year she suffered a severe and protracted flare up. Ruth attended a “very helpful” pain management programme in the 1990s.
- Pete reports having back problems for more than 10 years. He describes being aware of mild “twinges” in his back for some time before the sudden onset of a severely painful acute episode: “I could hardly walk for a few days and suffered great pain.” This episode took months to resolve. Pete still has recurrent episodes of low back pain, which he describes as “manageable”. He is employed.
- Anne has chronic low back pain, punctuated by flares. She describes first getting low back pain when she was in her 20's, as a result, she believes, of decorating, however, she believes her current problems stem from a later time when she was a carer. Anne is not currently in paid employment.

Box continues...

Box 5 continued. Participants' back pain stories.

- Tom had a sudden onset of “excruciating” pain 10 years ago after a long period of intermittent, mild back aches: “I wouldn't wish that pain on anyone.” It took a year for him to recover, since when he has experienced recurrent bouts of low back pain. He describes his current pain as a dull ache: “... not bad, but it threatens. I know I have to take care.” He is employed.
- Ginny is now retired and she describes pain as “a constant presence in my life to a greater or lesser extent at different times.” She began suffering recurrent bouts of low back pain as a young woman and has continued to do so ever since. At first she accepted these as normal but the episodes became more severe as time went on. She said there was a history of back pain in her family.

7.7.6. Discussion

The aim of this study was to explore back pain sufferers' experiences and perceptions of self help. It was observed from the slow recruitment to a self help intervention study for early, non-specific low back pain that there was an unexplained mismatch between the prevalence of the condition in the general population and the difficulty of finding people with early back pain who were willing to try a free, self help audio CD. The narratives of the interviewees in the present study may be interpreted in relation to the social cognitive variables believed to underlie deliberate health behaviours. Adopting self help to manage back pain is a deliberate health behaviour. A strong, positive intention or commitment to performing a behaviour, an absence of environmental constraints that would prevent performing the behaviour and having the necessary the skills to carry out the behaviour are believed to be necessary and sufficient factors for a health behaviour to occur. Five further factors - belief in some advantage or benefit to be accrued from performing the

behaviour, social norms, consistency with self image, a more positive than negative emotional response to the behaviour and perceived capability (self efficacy) to carry out the behaviour - are considered primarily to influence the first factor of intention (Fishbein et al., 2001). Such an interpretation may help to elucidate which factors may influence if and when back pain sufferers adopt self help strategies to manage their condition.

Interviewees referred to an initial period of time during which they had some back pain which was tolerable. Tolerable back pain seemed to be viewed as a normal part of everyday experience, such as an aspect of growing older and less supple or as an avoidable consequence of a particular action or activity. At this stage, there was no help seeking nor long term, pain management planning. The occasional, tolerable episode or an ongoing grumble of back ache seemed to be experiences with which one knew other people lived and which were accepted as a normal part of adult life. Thus at this stage, such people have not formed any strong, positive commitment or intention to experiment with managing their back pain. Social norms and a lack of belief in the benefits or advantages to them of adopting self help may have been contributory factors to an absence of intention at this stage.

Typically, interviewees recounted consulting a GP as a response to eventually experiencing a more severe and debilitating episode of low back pain. During this period of engagement with the NHS, participants' primary intention seemed to be to find a biomedical "cure" or "definitive solution" to what had now come to be perceived as a problem. However, interviewees recounted experiencing a mismatch between their expectations of medical interest and their hopes of a cure and the response they received from NHS professionals, which was often to be given painkillers and to be told to carry on as normal, as far as they could. NHS physiotherapy, if provided, was "too short". It may be observed that while NHS practitioners may have been attempting to implement a "biopsychosocial" approach to back pain management, this approach was initially neither shared nor well understood, according to accounts given by interviewees whose frustrations with medical professionals related to a lack of understanding from them of how profoundly their lives were affected by back pain and to the inability of the NHS to cure them. Participants told stories of repeated, return visits to NHS surgeries and of seeing different doctors in an effort to get help.

Qualitative findings reported in a Norwegian study (Glenton, 2002) also indicated a mismatch between patients' and doctors' expectations of back pain consultations. Content analysis of interviews with persistent back pain patients in Norway suggested several barriers to their accessing the type of information and support those patients wished, including time constraints of consultations, communication skill deficits and doctors and patients having different explanatory models for the back pain. Similar barriers for U.K. back pain patients are indicated by the present interviewees' recollections of their experiences of back pain consultation in the NHS.

Further, it seems from the participants' accounts that advice to stay active, which is in accordance with current, U.K. clinical guidelines (Hutchinson et al., 1996), can be heard by patients as dismissive - "you just have to put up with it" - or, in one instance, as an exhortation to begin vigorous exercise. Indeed, these interviewees stressed the importance of being helped to understand how not to aggravate back pain, particularly by learning as early as possible how to pace activities to avoid pain exacerbations.

GPs face a complex, information giving task in a 10 minute consultation with a patient with acute back pain. Staying active is evidence based advice (for example, Waddell et al., 1997). However, brief, general advice to stay active, in the context of a short, GP consultation in which the patient hopes for a medical cure, may be perceived as uninterested and unrealistic; many interviewees first consulted because they could no longer carry on activities as normal, despite having managed to do so in the past. It could potentially lead to severe, pain exacerbation if an individual interprets a recommendation to be active to mean to embark on new, vigorous exercise, despite increasing pain. On the other hand, being cautious and conveying that activities that are sore should be avoided may support the development of patients' fear avoidance beliefs and contribute to poorer outcomes for early back pain patients (Bishop et al., 2008). Advising a cautious approach to activity during an episode of non-specific low back pain may be a reflection of the health professional's own health beliefs (Vlaeyen, 2006). The findings here are concordant with research evidence from the U.K. and elsewhere, which has suggested that between 20 - 30% of primary care patients may fail to benefit greatly from the initial, brief, verbal reassurance and advice from a primary care practitioner (for example, Moore et al., 2000; Croft et al., 1998).

During the phase of NHS help seeking, environmental constraints and a lack of necessary skills may be the most salient barriers to adopting self help. Interviewees reported knowing very little about non-specific back pain or its management at this time. The NHS environment in which they sought help did not provide them with sufficient information to self manage their pain successfully nor direct them towards other resources from which they might have learned to accept a biopsychosocial understanding of back pain and learned about a range of possible, self help strategies. This interpretation accords with previously reported findings from a survey of public attitudes to health related self help in England, which found that being unsure about one's knowledge and understanding were barriers to individuals pursuing self help (DoH, 2005b).

One email interviewee embarked on self help because he wished to avoid doctors, whom he perceived would take a biomedical approach. He did not want to be given "drugs" or surgery. Others turned to self help only as a result of their experiences of the NHS and their perceptions of

its limitations. The data here do not illuminate the social cognitive factors that may underlie the transitional process for these individuals, who moved from one model of how their back pain should be handled – cured by the medical establishment - to another model, in which they started setting about finding ways to help themselves. For some interviewees, the change may reflect learning from attending a pain management programme – four of the interviewees here had attended such a programme in the past - while others achieved a similar transition without any such intervention. The data may illuminate some of the factors associated with the subsequent, relatively successful self management of persistent pain by these participants, however.

Having a belief in their ability to “take charge” in order to control their pain and its impact was an important element within the theme of control in these findings. Self belief in one's ability to exercise control would appear to relate closely to the social cognitive variable of self efficacy. Self efficacy is a psychological construct that refers to individuals' self evaluations of their capabilities of doing what is required to attain some outcome or goal. It is not a global self evaluation; rather, self efficacy beliefs are considered to be domain specific and to vary according to particular behaviours and circumstances. Domain specific self efficacy appraisals are implicated in the goals for which people strive, the persistence with which they pursue them and the likelihood of their achieving them. These interviewees' accounts of “trial and error” with regard to self help strategies were marked by considerable persistence, often over years. It appeared to be through persisting with “trial and error” that different individuals acquired the skills required to cope successfully with their own pain. The actual coping strategies used varied between individuals and at different times for the same individual. Participants recounted experiences with a range self help methods that included both problem focussed coping strategies (such as information and support seeking) and emotion focussed strategies (such as distraction by pleasurable activities) (Lazarus, 1999).

Coping is defined in the stress-coping model by Lazarus (1991) as:

“...cognitive and behavioural efforts to manage specific external or internal demands (and conflicts between them) that are appraised as taxing or exceeding the resources of the person...” (p. 112)

In the context of stress-coping, self efficacy refers to people's appraisals of their own capability successfully to carry out particular coping strategies. Previous research with other chronic pain populations has reported associations between self efficacy appraisals, coping strategies and outcomes, for instance, in rheumatoid arthritis patients (Rhee et al., 2000). Self efficacy appraisals can moderate the relationship between coping and emotional outcomes (Lowe et al., 2008). The role of self efficacy appraisals is acknowledged in CBT and has been incorporated into CBT based interventions designed to foster active self management. For example, the intervention to enhance self management of early back pain by Damush et al. (2003) consisted of classes that aimed specifically to increase participants' back pain related self efficacy beliefs. The current findings appear to lend support to an important role for positive self efficacy evaluations for successful self management of non-specific back pain. Higher self efficacy may allow the person with back pain to persist with experimentation with a variety of coping strategies and to base strategy selection and rejection on personal experience.

In addition to self efficacy, it may be speculated that other social cognitive variables may influence the initiation and maintenance of self help. The interviewees' accounts describe coming to believe in some advantage of self management in contrast to the perceived limitations of management of the condition within the NHS. Further, social norms, through coming to mix with others who were trying to manage back pain, such as other members of BackCare, and consistency with self image may also play roles. Interviewees alluded to managing a coherent sense of self as a "healthy" or "fit" person, despite living with ongoing and variable pain.

A potential barrier, or environmental constraint, to adopting and maintaining self management at this stage may be the financial cost of some the behaviours that were categorised as self help by interviewees, for example, paying for private physiotherapists and complementary practitioners. Interviewees' own and vicarious experiences of the expense of some self help strategies do not lend support to a speculative suggestion by the authors of a Department of Health report on public attitudes to self help (DoH, 2005b) that citing financial expense could be an excuse to mask lack of

motivation to engage with self care. These interviewees had become motivated to self care nonetheless recognised financial constraints could be a barrier to implementing self care.

The participants' interviews illuminate the way in which self management behaviours for coping with non-specific, low back pain may arise over time. The changing course of self help beliefs about managing low back pain was made explicit by one interviewee, who said: "My views on self help have changed. I am now convinced that there is no other way but self help."

Just as Smith & Osborn (2007) tentatively identified a developmental process in which chronic back pain patients battled to retain a positive sense of self, then became doubtful and, finally, resigned themselves to becoming a different and unwanted self, there is the suggestion of a developmental process here too. However, there appears to be an importance divergence between the processes reported in previous studies of chronic back pain (for example, Smith & Osborn, 2007; Walker et al., 1999) and those found among these interviewees. Most interviewees here, who are all managing living with chronic back pain relatively well, seem to move from accepting back pain as a normal part of life, to frustration with not finding a "cure" in the NHS, to turning to self help strategies for managing their own pain. Through the last, they report being able, by and large, to maintain a coherent and acceptable sense of self, typically of a "healthy" or "fit" self. Any "entrapment within the system", with its associated feelings of anger and bitterness (Walker et al., 1999), was a phase in the process. Further, these interviewees report using social comparisons in a more positive way than the equivocal use of social comparisons found in chronic pain patients in the study by Osborn & Smith (1998). The participants in this study were able to feel relatively well off by comparing themselves to those dealing with more difficult back pain problems, while social comparisons also seemed to serve to foster a sense of belonging to a diverse community of back pain sufferers.

7.7.7. Conclusion

It is suggested that people's management of living with non-specific back pain is a developmental process over time, related to the variable course of the condition. While the findings reported here may be specific to the small group of individuals interviewed by email for this study, their narratives offer some insights into the processes that might influence when a back pain sufferer may initiate self help strategies for pain management. The study was an exploration of individuals' experiences and perceptions of self help, with the aim of illuminating some of the subjective processes that may impact on the early use, or not, of self help for back pain. It appears from these interviewees' accounts that neither help seeking from the medical profession nor self help are likely to be initiated in the first instance, particularly if the back pain is intermittent or the pain intensity is considered tolerable. Help seeking from the NHS may be prompted only by a more severe episode of back pain and, at that stage, there may be a mismatch between the help seekers' expectations of understanding of the impact of back pain on their lives and of a solution and the responses they perceive from NHS health professionals. A turn to self help may be a third stage in the process, perhaps as a response to feelings of frustration with NHS care for non-specific low back pain. It is tentatively suggested that in the first stage, lack of intention may be the most salient, social cognitive variable in not implementing self help, whereas in the second, NHS help seeking stage, environmental constraints and patients' lack of self help skills and knowledge appear to be salient factors.

If this interpretation is correct, there are implications for very early self help interventions for non-specific low back pain sufferers. Very early interventions may not be seen as useful or relevant to those currently living with tolerable, intermittent back pain. If sufferers go on to seek help from the NHS, however, there may be opportunities for health professionals then to play a role in educating patients and guiding them towards self help resources. It has been reported elsewhere that the most trusted and favoured source of information and support for health related self help is the GP; it is also reported that family doctors are not currently perceived to be providing much by way of information nor encouragement for greater self care (DoH, 2006; DoH, 2005). Those findings accord with the findings reported here, including that interviewees wish with hindsight that they had

been educated to assume greater responsibility for managing their back pain, early on, by an NHS health professional. The relationship between a retrospective desire for early encouragement and support for self help and actual behaviour among early back pain patients if they were offered such encouragement and support is not clear. Nonetheless, it may be concluded that there is potential for improving Step 1 in a stepped care treatment model (Von Korff, 1999) for non-specific low back pain in U.K. primary care. Turning to primary care may often be the first help seeking behaviour and potentially offers opportunities to educate patients in a biopsychosocial understanding of a condition that may be persistent, fluctuating and recurrent as well as to introduce ideas of self help for its management.

With reference to the question that prompted this study – why it was difficult to recruit members of the general public to an early self help intervention for non-specific low back pain - the likely answer would appear to be that, without greater acceptance among the public of the biopsychosocial nature of back pain and greater public and professional awareness of the often persistent and sometimes deteriorating, natural course of non-specific low back pain, very early back pain sufferers simply do not perceive the need; they do not perceive they may have a “problem”. As Ruth said: “At the beginning, it is hard to accept you have a problem...” (R/1.3)

8. Chapter Eight. Discussion.

8.1. Introduction

The researcher set out with the aim of investigating whether a standardised, CBT based intervention for early low back pain had the potential to improve current, Step 1 care for non-specific back pain patients. The results of a pragmatic, randomised controlled trial of effectiveness of self help, audio CDs, which provide information and reassurance and encourage active self management, may be interpreted as supporting the argument in this thesis that there may be potential for improving the current, “watch and wait” management of acute, non-specific low back pain for which help is sought. Use of a self help CD by people with an episode of early back pain in the community was associated with significantly improved functional outcomes at six months. In this chapter, the findings from each of the three phases of the thesis research – a pilot evaluation of new audio CDs to enhance self management of early, non-specific back pain; a pragmatic, randomised controlled trial of their effectiveness in the community; and an exploration of people's accounts of using self help for back pain - will be discussed in turn before considering what the thesis findings, taken together, contribute to knowledge about non-specific low back pain and its early management. Research limitations are highlighted and future research directions suggested.

8.2. Pilot evaluation of “Using Relaxation Skills” and “Using Thinking Skills” audio CDs

The principal objective of the pilot evaluation was to assess whether the new, self help programmes for home use were easily used, understood and considered to satisfactory by users. It showed that the format and content of both CD programmes could be highly acceptable to primary care patients with early, non-specific low back pain.

The format of the home based, self help, audio CDs recognised the time pressures on NHS GPs in routine consultations; questions concerning the adequate delivery of planned, psychosocial interventions by health practitioners with minimal training in intervention delivery (Macfarlane et al., 2006); and the influence of variations in therapists' characteristics in interventions delivered face to face (Morley & Williams, 2002).

The pilot evaluation showed the relaxation programme to be unanimously well received whereas the thinking skills programme received a more mixed response. The greater appeal of the relaxation programme may relate to the familiarity of audio delivered relaxation programmes – commercial relaxation and meditation CDs are widely available and apparently popular, at least among some sections of the population – and may relate to the attraction of “helping” oneself by spending time relaxing. The six participants in the pilot evaluation, including one who was “extremely satisfied” with “Using Thinking Skills”, said they liked the idea of taking time out from their daily lives to spend quietly alone in relaxation. The reasons for the particular appeal of relaxation as self help were not articulated further but perhaps may be interpreted as reflecting participants' feelings of trying to cope with a number of pressures in their daily lives, including back pain. Relaxation training and identifying and modifying unhelpful links between feeling, thinking and doing, or cognitive restructuring, are both components of CBT for pain management (Linton & Ryberg, 2001). The more intellectually challenging component of cognitive restructuring, covered in “Using Thinking Skills”, may be perceived as giving additional work in a personal life that is already experienced as demanding, whereas the “Using Relaxation Skills” may be perceived as offering some respite.

It is acknowledged that there will be people who are not motivated to undertake health related self help and, in addition, that aspects of CBT based, self help programmes will not be suitable for everyone. Previous findings of socio-economic deprivation and low educational attainment undermining motivation and capacity to self care (DoH, 2005a; DoH, 2005b) appeared to be supported in this small, pilot evaluation, in which a woman who reported finding it difficult to complete the reading and writing involved in the homework exercises for “Using Thinking Skills”

had no formal, educational qualifications. Notwithstanding, the enthusiastic response of a graduate to the thinking skills programme indicated that the choice of programmes should be retained, and that personal preference could be a reasonable guide to which of the self help programmes an individual who was motivated to self manage back pain should use. The desire for programme choice was expressed by the pilot evaluators. Goossens et al. (2005) found that treatment expectancy affected outcomes in CBT interventions in chronic pain patients; exercising choice over the content of a CBT based, self help intervention might influence early back pain patients' adherence to a home based, audio CD programme and consequently influence observed outcomes.

No reports of similar evaluations of new, self help materials based on CBT for acute low back pain were identified in the literature. One relevant, primary care study in The Netherlands, which also sought to improve outcomes for acute, non-specific low back patients, differed from the current, pilot evaluation and subsequent, pragmatic randomised controlled trial of effectiveness in important respects (Jellema et al., 2005a). The Step 1 intervention by Jellema and colleagues was not based on CBT for pain management but on training GPs to identify and modify adverse, psychosocial indicators in an extended consultation. It found no statistically significant effects compared to usual GP care. The authors later reported that the intervention arm GPs had been only moderately successful at identifying individuals' psychosocial risk factors (Jellema et al., 2005b). However, assuming that identifying and modifying any particular, psychosocial risk factor at Step 1, before such variables become stable and possibly maladaptive, is not well supported by the limited, available evidence on early, risk factor fluctuation (Sieben et al., 2002; Enthoven et al., 2003; Dunn & Croft, 2006) and on early intervention based on modifying specific, psychosocial risk factors (George et al., 2003; Klaber Moffett et al., 2004). Interventions with that focus, and with treatments matched to patients, may be more appropriate for Step 2 treatment for sub acute back pain patients (Brennan et al., 2006; van der Windt et al., 2008). The pilot evaluation of the self help materials produced for this thesis indicated that a Step 1 intervention that aimed to give information, reassurance and skills education for pain management, and that did not aim to address any single, psychosocial risk factor, was satisfactory to primary care patients and could be delivered by audio CD for use at home.

An important finding from the pilot evaluation concerned a secondary objective of assessing the practicability of using an NHS GP setting for an effectiveness trial of the new, back pain CDs.

The process of identifying GP participants for the pilot evaluation and of obtaining necessary, ethical and management approvals transpired to be a protracted process and it was followed by serious difficulties with enrolling eligible, GP patients. Intensive efforts to follow up possible, patient recruits, who were identified in routine consultations by seven, participating GPs, yielded only six enrolments into the pilot evaluation in six weeks. Difficulties with recruiting were anticipated

because they had been previously reported by primary care researchers in the U.K. (Klaber Moffett, 1999; Bell-Syer & Klaber Moffett, 2000; Hay et al., 2005); the NHS Lothian Primary Care Research and Development Committee had also indicated likely difficulties with primary care recruitment in the region. Notwithstanding, the severity of the recruitment problem and its implications for the successful completion of the thesis research had evidently been underestimated. It had been anticipated that, even if only an estimated one in five of those experiencing an acute episode of non-specific low back pain consulted a GP (Papageorgiou & Rigby, 1991), the reported prevalence of the condition in the population was so high - most adults will be affected by it at some time (Dionne, 1999) - that primary care would provide a large pool of potential, Step 1 intervention participants. The rationale for the research was the possibility of improving Step 1 of stepped care for NHS patients consulting with acute, non-specific low back pain, however, the slowness of recruitment observed in the pilot evaluation indicated a serious problem for carrying out a proposed, effectiveness trial in primary care in Scotland.

There is an emphasis on evidence based practice in NHS health care, an emphasis which underpins the recently introduced, new NHS contract for Scottish GPs. Opportunities for improving the current evidence base for primary care practitioners would seem, however, to be largely limited to larger scale, funded studies that contribute to the Scottish Office's Support for Science agenda. The implications for individuals endeavouring to undertake smaller scale research locally in primary care, for which previously available support has now been withdrawn by the Lothian and Borders Primary Care Research Network, were evident in the difficulties experienced here with recruiting GPs and their patients for the CD pilot evaluation. Personal contacts led to the enrolment of one, large GP practice with seven partners yet this proved insufficient to access adequate numbers of eligible patients in a practicable time scale for a randomised, controlled trial requiring a larger sample size. Slow recruitment may be exacerbated by a researcher working off-site and therefore relying on busy doctors, whose priority in the patient-doctor consultation is not research recruitment, to identify potentially eligible participants.

A possible amelioration of this difficulty may lie in researchers who are not employed within the primary care setting in which the research is being pursued choosing to focus on health conditions that are computer coded under the new GP contract; researchers would first require ethical and management approval to access patients' electronic records to identify possible candidates for their research project through electronic searching. Alternatively, it might be speculated that research projects initiated by the primary care practitioners themselves, and in which the GPs took written, informed consent from the patients, might show improved recruitment rates. A number of patients who had expressed willingness to have their names put forward as potential participants in the pilot evaluation when in the consultation room with the GP later declined to enrol or did not respond to the researcher's subsequent approaches. If socially desirable responding were to play a role in increasing research recruitment where consent is taken by the GP, ethical issues relating to such research participants' informed consent would require to be given consideration.

Given the available resources and time limitations for the thesis research, it was recognised that it was impractical to pursue an effectiveness trial of the self help CDs in Scottish, GP surgeries, as had originally been planned. Rather, an exploratory trial of the effectiveness of the self help programmes for managing early back pain would be carried out in the community, where, it was hoped, research participants would be recruited more readily. The aim of the proposed effectiveness trial was to demonstrate whether a CBT based, self help, audio programme, providing reassurance and information about non-specific low back pain and encouraging early self management, showed benefits with respect to back pain specific functioning, general health and well being and self reported pain intensity. It is likely that those who choose not to consult differ in some ways from those who do, for example, in pain intensity or psychological distress (Macfarlane et al., 2006). Nonetheless, a pragmatic, randomised controlled trial in the community would provide information on whether the new intervention materials for early back pain were practicable and had benefits for people living with acute, non-specific low back pain outside a clinical setting. The findings could then be related, if appropriate, to Step 1 management in primary care.

8.2.1. Main points

- The format and contents of self help audio CDs, giving information and reassurance and teaching skills components from CBT (relaxation skills; problem solving, activity pacing and identifying and challenging unhelpful thoughts) are acceptable for home use to primary care patients with early, non-specific low back pain
- CBT based programmes and self help are unlikely to be appropriate for everyone
- Recruiting into research in an NHS primary care setting is problematic

8.3. Pragmatic, randomised controlled trial of the effectiveness of self help, audio CDs for early, non-specific low back pain

The trial results showed that, compared to controls, participants using a self help audio CD at home showed significantly improved back pain specific functioning over time ($F=6.673$, $p=.013$). No other, significant differences were demonstrated between the intervention and control groups. Both study groups demonstrated significant improvements between baseline and six month follow up with respect to back pain specific functioning, pain intensity, physical health and well being and mental health and well being, highlighting a natural recovery or amelioration of symptoms in the months following back pain onset. It was concluded that a three week, home based, self help programme delivered by audio CD had the potential to significantly improve functional outcomes in early, non-specific low back pain, although the observed effect size was small (partial eta squared=.137). Benefits are likely to be restricted to those individuals with early, non-specific low back pain who are motivated to engage with CBT based, self help, audio programmes.

Participants randomised to the intervention arm chose one of two programmes, “Using Relaxation Skills” or “Using Thinking Skills”, based on personal preference. All of the participants who completed a self help programme (22/23) reported being satisfied ($n=2$), very satisfied ($n=14$) or extremely satisfied ($n=6$) with their chosen audio CD. The majority (17/23) elected to use the “Using Relaxation Skills” audio CD, which was concordant with preliminary indications from a pilot evaluation that “Using Relaxation Skills” would have wider, popular appeal.

Currently, U.K. clinical guidelines advocate a “watch and wait” approach to early back pain management (van Tulder & Koes, 2006), based on assumptions of good prognoses for the vast majority of low back pain patients. In line with previously reported studies (Croft et al., 1998; Thomas et al., 1999; Pengel et al., 2003; Jones et al., 2006), the current trial demonstrated the variable and often persistent nature of acute episodes of non-specific low back pain, despite a trend for natural recovery; 71% of trial participants reported residual, albeit often greatly improved, back pain related symptoms at six month follow up.

The current findings also lend additional, limited support to preliminary evidence (Wand et al., 2004) to challenge current “watch and wait”, Step 1 care for acute, non-specific low back pain patients in the U.K. Wand and colleagues reported that, compared to the standard assess, advise and wait model, acute back pain patients significantly benefited from quicker referral to biopsychosocial physiotherapy. Recruits to the study by Wand et al. (2004) had non-specific low back pain that had lasted up to six weeks. Those in the early, active treatment arm showed significant improvements in pain and disability at follow up at six weeks, although the benefits observed in the early referral group were not sustained. In the current research, where participants were enrolled with non-specific low back pain of up to nine weeks' duration, a significant difference between the intervention and control groups was observed for back pain specific functioning and this benefit to the intervention group was maintained, slightly attenuated, at six months. The contents and formats of the early intervention for acute, non-specific back pain reported here and in the intervention study by Wand and colleagues differ markedly from one another, which makes it hard to draw direct comparisons and to interpret the different findings. Nonetheless, both studies may be said to give some support to the potential benefit of earlier, active treatment in the acute phase of non-specific low back pain.

Although no directly comparable studies to the current study could be identified, the CD intervention trial may be considered in relation to two, previously reported trials that were also concerned with acute, non-specific back pain and CBT.

A Swedish trial compared usual GP care of assess, reassure and advise with an intervention group who received group CBT in addition to physical therapy and a third group who received group CBT without physiotherapy (Linton et al., 2005). Group CBT was delivered by trained therapists in accordance with a manual. The authors reported that those in both of the group CBT arms demonstrated significant benefits with respect to pain related disability at one year follow up. Again, direct comparison is unwarranted. The study by Linton et al. (2005) was a larger trial (n=185), with different outcome measures and face to face, group CBT as the intervention. The study's outcome measures were work absenteeism and health care use, and participants were enrolled with back or neck pain. Components of the group CBT programme – education about back pain, relaxation training, problem solving, activity pacing and looking at cognitive appraisals and beliefs – were similar to the elements of the self help programmes on the audio CDs, however. It may be said that the current findings of benefit from the audio CDs for back pain specific functioning do not contradict the findings of benefit from group CBT for acute back or neck pain reported by Linton et al. (2005). Together, the findings may be interpreted as supporting an argument for early, active treatment in acute back pain and for the potential benefits of CBT based interventions.

A third study that it is relevant to consider in relation to the CD effectiveness trial is the intervention research carried out with socio-economically deprived members of the community with acute, non-specific low back pain in the U.S.A. (Damush et al., 2002; 2003). Recruits to this study had back pain of up to 12 weeks' duration. The planned intervention programme, similar in concept to the content of the audio CDs, was based on CBT for pain management and aimed to enhance self management (Damush et al., 2002). The intervention was conceived as a series of face to face classes, however, the authors reported posting audiotapes of the intervention materials to the majority of participants in an effort to retain recruits (Damush et al., 2003). Several limitations of the study, including repeated adjustments to its design, a high loss to follow up and a main outcome measure that is not validated for use in the non-specific low back pain population, suggest the study findings should be viewed cautiously. The authors reported significant benefits of the CBT based intervention in terms of improved physical and mental functioning and improved self efficacy beliefs with respect to managing low back pain symptoms. Despite the limitations of the U.S.A.

study, the current trial findings and the findings reported by Damush and colleagues offer preliminary support for CBT based, audio programmes designed to enhance self management in acute low back pain, particularly with respect to improved functional outcomes.

The combined evidence (Wand et al., 2004; Linton et al., 2005; Damush et al., 2003) lends support to initiating active intervention in the acute phase of non-specific low back pain, in contrast to the current U.K. practice of assess, reassure and wait. The available evidence is limited and not strong, nonetheless, preliminary evidence, to which the current, CD trial contributes, is accumulating and justifies questioning an exclusive focus on improving outcomes in non-specific low back pain by intervening only at Steps 2 and 3. The audio CD effectiveness trial in this thesis, which demonstrated significantly improved, back pain specific functional outcomes at one and six months, also supports active intervention in the acute phase if improved, back pain outcomes are to be achieved. A claim for benefit from introducing self help, audio CDs at Step 1 of primary care management for acute back pain would have to be made cautiously, however; it has not been demonstrated that the findings of functional benefit observed in a community sample would be generalised to a primary care population, who may differ in some important respects.

The magnitude of the observed effect size in the trial was, as anticipated, small. The variable course of new or recurrent episodes of non-specific low back, with spontaneous recovery for some within the first weeks of onset, will make it more challenging for researchers to find significant effects of any early intervention (Frank et al., 1996; Pengel et al., 2003). When a condition is as prevalent in the population as non-specific low back pain (Dionne, 1999; Koes et al., 2006), observed, small effect sizes may represent worthwhile intervention benefit, and findings of modest, overall effect for a condition in which the aetiology, individual risk factors and prognosis are heterogeneous may conceal substantial benefit for some individuals. As Macfarlane et al. (2006) write:

“... it may be that our expectations of outcome in studies of back pain management have been too high. ... For a condition that is very common , with a multi-factorial aetiology it may be that we should consider small, medium and long term changes in pain and function as realistic measures of success.” (p. 221)

Participant recruitment posed difficulties in the pilot evaluation and the subsequent, effectiveness trial. Research problems and limitations are outlined in Box 6. The expectation that the recruitment rate in the community would be much higher than in primary care was not met. Recruitment was notably slow and failed to reach its target sample size of 74. If a study is under powered to detect any differences that do exist between groups, it is hard to draw conclusions about what reported, non significant findings tell us. Nonetheless, the smaller sample size (n=44) for the study was adequate to detect a significant, between group difference on measures of back pain specific functioning. The non significant finding for relatively greater improvements over time in mental and physical health and well being in the intervention arm is harder to interpret. It may be that the smaller sample size meant important, between group differences could not be detected, or it may be that there were no significant, between group differences in these domains as measured by the SF-12v2. If the latter, this may reflect the observed, significant improvements across all measures over time for all participants, regardless of group allocation, despite incomplete resolution of symptoms for the majority.

A variety of recruitment strategies was tried for this trial, including circulating information in workplaces with large numbers of employees and advertising to the public through posters and newspaper notices. In all cases, the response was poor. As in the pilot evaluation of the self help, audio CDs in primary care, recruitment was a significant difficulty in the community trial of CD effectiveness.

Box 6. Problems and limitations with the research.

Difficulties with recruiting into the trial

Failure to meet target sample size

Researcher and participants not blinded. Possibility of unconscious bias.

Extreme outlier in the data set and substitution of observed scores with group mean score. Possibility of bias.

Can the findings be generalised to primary care?

In addition to the failure to achieve the target sample size, a weakness to be considered is the possibility of unconscious bias; the same researcher was responsible for recruitment, randomisation, group allocation and follow up throughout the study. Bias may also have been introduced into the findings by the selected strategy to deal with an extreme outlier in the data set. There is not a perfect solution to this problem and there are advantages and disadvantages to all the possible strategies of cleaning the data set of outliers, retaining outliers' observed scores and retaining outliers with adjusted scores substituted for the extreme scores or choosing a less powerful, non-parametric analysis. The strategy chosen in this instance allowed more powerful, parametric statistical analyses to be undertaken without depleting the relatively small data set, nonetheless it is recognised that any method for substituting extreme, observed scores may influence the reported findings. Further, the initial aim had been to carry out the research in a primary care setting. It is likely that there will be some differences between members of the public with acute, non-specific low back pain who choose to consult and those who do not, for example, with respect to the intensity of the pain they are experiencing and to levels of psychological distress (Macfarlane et al., 2006). While the findings reported here support the proposition that there is potential to improve outcomes by an early intervention in non-specific low back pain, it is less clear that the findings can be generalised to Step 1 care for back pain management in a primary care population.

The trial was a pragmatic, randomised controlled trial to investigate the effectiveness of the new audio CDs. The outcome measures did not attempt to gather data to illuminate the processes underlying any observed changes in back pain related outcomes. Future research questions concern the mechanisms for the observed benefit. For example, two studies have reported changes in back pain related self efficacy beliefs following CBT based interventions designed to enhance self management for back pain (Moore et al., 2000; Damush et al., 2003). If further research were undertaken with the self help, audio CDs, it would be useful to include a validated measure of self efficacy beliefs and to assess back pain related self efficacy appraisals at baseline and follow up. In this study, both mood and pain intensity at baseline were found to make an independent and significant contribution to back pain specific functioning, as measured by the RDQ. Mood was only assessed at baseline, as a screening instrument to exclude participants with severe depression. Further work could usefully include repeated measures of mood, as well as domain specific self efficacy beliefs.

Additionally, the trial design could be improved by an approach to group assignment other than randomisation using computer generated lists of numbers. The inclusion criteria for the current trial included a wide age range of between 20 and 65 years, which reflects when non-specific low back pain is most common. The range acknowledged the need not to hamper recruitment and that the current, effectiveness trial was pragmatic and exploratory in nature. An efficacy trial would benefit from “minimisation” (Simon, 2006), an approach in which any covariate imbalance is minimised at each stage of group assignment. Throughout the trial, recruits are allocated to maintain a balance between control and intervention participants, for example, on age, baseline pain intensity and baseline mood. Advantages and disadvantages of minimisation versus randomisation are discussed in Simon (2006).

8.3.1. Main points

- A three week, self help, audio CD to enhance self management of early, non-specific low back pain demonstrated significant benefits with respect to back pain specific functioning at one and six months
- Intervention effects of small magnitude may represent worthwhile interventions in highly prevalent conditions, such as non-specific low back pain
- It is not clear that the findings of audio CD benefit in a community sample can be generalised to a primary care, back pain population
- Recruiting into a community trial was problematic

8.4. IPA investigation into self help for back pain

The difficulties with recruitment into a trial of self help, audio CDs for early back pain management raised new research questions. The researcher felt it would be helpful to try to understand why there was not a better uptake of free CDs designed to enhance early back pain management when non-specific low back pain is so common in the general population. A further study was planned to explore individuals' experiences and perceptions of self help with the aim of illuminating some of the processes that may influence the early use, or not, of self help for back pain management.

In an IPA analysis of email interviews with people whose back pain had persisted some years, it emerged that turning to self help may be a developmental process, related to the variable nature of back pain symptoms. Interviewees wished with hindsight that they had been encouraged and supported in self care for back pain when they had first consulted a GP, while also describing having a biomedical approach to their back problems at that time. They had consulted a GP in the hope of a "cure". Evidence from elsewhere in the U.K. supports the important role of health professionals, particularly GPs, if health related self care behaviours are to be enhanced (DoH, 2005a; 2005b; 2006). The GP is the preferred source of information and support for health related self care (DoH, 2005b). According to Linton (2002), a primary care consultation is likely to offer the

best opportunity to intervene to improve back pain outcomes because patients who consult may be motivated to take part in treatments. Nonetheless, few GP surgeries in the U.K. may offer much information or support for greater self care (DoH, 2006). The brief advice and reassurance offered by “biopsychosocial” management in a GP consultation neither encouraged self management nor met expectations of medical help in the accounts of these interviewees, who recalled communication failures and frustrations with the NHS care they received.

Turning to the NHS for help was typically after a long period during which back pain had been accepted as normal and tolerable; doctor appointments were made when interviewees came to perceive they had a problem that was no longer tolerable, often related to increased pain intensity and to the adverse impact of back pain on their lives. For many, the turn to self help came considerably later again, when the available treatment from the NHS had come to be viewed as inadequate and alternatives were sought.

The interview study sought to illuminate the apparent lack of public interest in a free, self help programme for early back pain. The interview findings suggest the answer may lie in a perceived lack of need for any help in the early stages of non-specific low back pain. People living with tolerable, acute episodes of low back pain may be unlikely to seek any treatment, including “medical” treatment from the NHS and self help treatments. Self help programmes for use at this stage may not be viewed by the public as relevant or useful. It was only with hindsight that interviewees expressed a wish that they had been directed to information and resources to support self management at an early stage of their back pain. It can only be speculated whether self help behaviours and back pain related outcomes would have been positively influenced had this been the case.

Linton (2002) identified the first, primary care consultation as an opportune time and place for early intervention for non-specific low back pain. The interviewees' accounts highlighted that the help they had hoped to receive when first consulting was medical help and a “cure”. Primary care staff may be well placed to encourage a biopsychosocial understanding of back pain and to initiate

support for early self management, perhaps by guiding patients to information and self help resources beyond the NHS surgery, as some of these interviewees suggested. However, encouragement to try self help was not the experience reported by interviewees in the study, which accords with evidence that patient self care is not currently well supported in U.K. primary care (DoH, 2006). Without education and encouragement from a health professional, it seems likely that many, early back pain patients will not initially consider self help, even when back pain has become a problem that has led to NHS help seeking. A potentially effective self help programme for early, non-specific low back pain will only be effective in the real world if people have the knowledge and motivation to try self help approaches; from these interviewees' accounts, this may not be the case for many people in the early stages of non-specific low back pain.

In an IPA analysis, the idiographic perspective is paramount (Smith et al., 1997), however, having more than one participant's account allows the researcher to consider ways in which several idiographic narratives converge and diverge (Shaw, 2001). A common theme in these interviewees' accounts - of living with tolerable back pain for some time, then engaging with the NHS once the back pain became perceived as a problem and only later turning to self help, often as a response to the perceived limitations of NHS care - allowed this researcher to conclude that embarking on self help strategies for back pain may be a developmental process over time. This is a plausible conclusion and grounded in the email interview data. Nonetheless, it is recognised that different participants, interviewed at different times, would have offered different narrative accounts and therefore may have suggested alternative or additional insights into the slow uptake of free, self help CDs for early back pain.

From the data gathered here, it seems reasonable to suggest that a self help programme for early back pain is unlikely to have wide appeal among the general public when the need for any intervention may not be perceived. A primary care consultation would seem the ideal time to encourage people consulting with non-specific low back pain to initiate self help; enhanced, early self management from using a home based, self help audio CD programme has the potential to improve functional outcomes for those to whom CBT based, self help materials appeal. The

resulting benefit may be modest but nonetheless worthwhile given the condition's prevalence. Any potential for benefit is likely to remain unrealised unless there is better education, information and support for self management given by primary care health professionals when people with early, non-specific low back pain first consult.

8.4.1. Main points:

- Turning to self help for non-specific low back pain may be a developmental process over time, related to the course of the condition
- People living with early, tolerable back pain may perceive no need for any form of help or treatment; a self help intervention at this stage is unlikely to be perceived as relevant
- There is a potential opportunity to educate and to encourage initiating self help strategies if people with non-specific low back pain seek help from the NHS

8.5. Conclusions

Taken together, the findings from the three investigations reported in the thesis draw a circle that starts and ends with Step 1 care for early, non-specific low back pain. A three week, home based, self help programme delivered by audio CD has potential to improve short to medium term, functional outcomes in non-specific low back pain, which is a very common and costly condition. Such audio CDs have been found to be well received by primary care patients in a pilot evaluation and by those members of the public who are motivated to enrol in a CBT based, self help trial. The observed, clinical benefits of the audio CDs may have the potential to divert some with early, non-specific low back pain from declining into chronic pain and disability. However, a CBT based programme is unlikely to be suitable for everybody and substantial numbers of people living with low back pain may not be motivated to engage with any self help programme. Reasons for people with early, non-specific low back pain not pursuing self help may include not perceiving they have a problem, perceiving they have a medical problem and not having the knowledge and support they would need to implement self management.

The first consultation with the GP would appear to offer the best prospect of timely support and encouragement for self care for early, non-specific low back pain, and inexpensive self help materials for use outside the surgery, such as audio CDs, are one, potential way of providing such a service. It had been intended to research the effectiveness of the audio CDs in primary care to investigate possible improvements to Step 1 care of stepped care management – an area where there is an absence of U.K. research to date. This proved not to be possible because of difficulties with recruiting in NHS primary care. Difficulties with recruiting for the effectiveness trial were also experienced in the community. A qualitative investigation of when and why people might turn to self help indicated that those who come to perceive they have a problem with their back pain may first turn to the GP, often hoping at that point for a “medical cure” - which returns the focus to Step 1 care.

It may be concluded that there is some potential for improving outcomes in acute, non-specific, low back pain by early intervention with self help, audio CDs that are based on CBT. However, the

observed effect size for functional benefit is small and the uptake of such self help programmes by the general public is low. The problems with carrying out research in primary care, where such CDs might theoretically play a wider role if patients were encouraged to try them - and thus contribute to improving Step 1 of stepped care for some patients - makes establishing a robust evidence base for their use in the NHS unlikely in the near future. Their potential to have a significant impact on the widespread problem of back pain throughout U.K. society therefore seems limited in the current context of limited support for primary care research combined with an NHS focus on evidence based medicine (EBM). Nonetheless, it is strongly recommended that Step 1 care should no longer be excluded from the research agenda; possible enhancements to current management at Steps 1, 2 and 3 should all be given consideration if outcomes in non-specific low back pain are to be improved.

The current work contributes to knowledge in two, important areas. Firstly, it has highlighted the evidence gap with respect to possibly improving back pain outcomes by intervening in the acute phase, when individuals' adverse psychosocial prognostic factors may potentially be diverted from becoming entrenched and maladaptive. It has demonstrated that one such intervention, a CBT based, self help audio CD, has potential to improve functional outcomes in the short to medium term. Secondly, it contributes to the field of health psychology research by an innovative use of mixed methods that combines IPA and quantitative methodologies.

IPA is a qualitative methodology that has been widely used in health psychology (Brocki & Wearden, 2006). To date, it has been employed as a 'stand alone' research process to investigate participants' "insider" perspectives (Smith et al., 1997) of a variety of health related experiences. Arguments for and against mixed designs continue to be debated by researchers from several disciplines, including from psychology. The use of a randomised controlled trial (RCT) and an IPA study in this thesis suggests it is a combination that may have much to offer health psychology research.

The observation that combined IPA and quantitative findings have not previously been reported in published studies may reflect a conventional, qualitative-quantitative side-taking more than any philosophical or practical incompatibility. Both methodologies reside comfortably in a broadly realistic ontology, in which measurable, quantifiable knowledge and negotiated, subjective sense making of a real world are simultaneously acknowledged. Some link between the objective (quantitative) and subjective (qualitative) is generally assumed by social cognitive health psychologists. For example, from a social cognitive perspective, it is assumed that some relationship exists between an individual's social cognitions relating to his or her bodily experiences, the language used to communicate those social cognitions to others and the real, physical entity of a body living in the world.

The subjectivity at the heart of idiographic IPA work is not necessarily at odds with the supposed objectivity of quantitative RCTs. Indeed, controlling and randomisation in quantitative RCTs may be understood as an implicit recognition of the influences of human subjectivity and a need in quantitative research to try to minimise biases that subjectivity can introduce. Both statistical and IPA analyses employ rigorous, systematic procedures to make sense of collected data (Hanson, 2006). The external validity, or generalisability, of findings from each methodology is different but not fundamentally incompatible: RCTs use population samples to generalise to the whole population of interest, which is normally restricted to a sub-set of the entire population, defined by the restrictions of the participant inclusion and exclusion criteria; IPA findings from multiple participants do not claim to be generalisable in the same way yet nonetheless aim to illuminate subjective experiences and processes that may develop health psychologists' understanding of people beyond a particular IPA sample and in other health related contexts (Smith & Osburn, 2003).

Using the RCT together with an IPA study to investigate a health related topic may be considered a novel form of research triangulation, where the different, methodological perspectives taken together advance knowledge more than either approach on its own. Triangulation itself is linked to notions of objectivity; it aims to produce a broader or deeper but nonetheless coherent and

integrated account of a research topic. Hence, just as recognition of subjectivity is not necessarily the preserve of qualitative methodology, aspirations to objectivity are not necessarily the preserve of quantitative methodology. For the social cognitive health psychologist, who assumes some relationship between the subjective and the objective, there is an opportunity to develop triangulation in research to include triangulating quantitative and qualitative, IPA methodologies.

Considering findings from both methodologies offers the prospect of testing the quantitative outcomes of psychological models and interventions in tandem with gaining improved understanding of the mechanisms underlying the observed results. Further, it may help to identify constructs that may be missing from current models and contribute to the development of better models and interventions. Closer collaboration between qualitative and quantitative health psychologists has been advocated before (for example, by Thompson et al., 2002), however, additional benefits of combining macro and micro level research may be realised by viewing a research topic through an RCT and an IPA lens simultaneously. This goes beyond a more traditional, mixed method approach in which, typically, qualitative work precedes quantitative work. For example, interview or focus group findings may be used to formulate a questionnaire survey, which is then administered to a target population and the ensuing data analysed quantitatively.

The combination of an RCT and an IPA study in this thesis provided insights into the quantifiable effectiveness of an early intervention for non-specific low back pain alongside insights into the practicability of such an intervention in real world conditions. The rationale for exploring if, why and when people with back pain might be motivated to engage with a self help intervention arose from the difficulties with enrolling acute back pain participants into the self help, intervention trial. Similarly, future IPA studies could be combined with related, quantitative studies to illuminate the subjective processes underlying not only trial recruitment but also, for example, intervention adherence and variations in outcomes that are otherwise lost in reported means. Such combined data generation is conceptually similar to realistic evaluation, in which the aim is to ascertain what works (and does not work) for whom and in what circumstances. Linking RCT and IPA research findings may go some way towards addressing one of the criticisms of EBM in which RCTs

dominate a hierarchy of evidence (Simon, 2006), namely the difficulty for health practitioners of translating the averaged outcomes of systematic reviews or single, large RCTs into appropriate management for an idiosyncratic individual in a particular socio-cultural context (Lean et al., 2008).

Recommendations for future research therefore include further conceptual consideration and practical investigations of the potential contribution to health psychology of mixed designs in research, specifically the simultaneous combination of qualitative IPA methodology and quantitative RCTs.

In addition, specific research topics that merit future investigation were revealed in the review of the literature and in the findings of the IPA investigation for this thesis. In the first instance, recent investigations by French researchers (Coudeyre et al., 2006, 2007; Poiraudau et al., 2006) and U.K. researchers (Bishop et al., 2008) into the health beliefs of doctors strongly suggest that the influence of health providers' beliefs about non-specific low back pain, and if and how these influence their patients' health beliefs and subsequent outcomes, is an important area that requires further study.

In the second instance, and related to the first, interesting research questions about doctor-patient consultations for acute low back pain arise from the qualitative data collected for this thesis. Given participants in the IPA investigation describe visiting a GP when the impact of back pain on their lives had become a problem for which they hoped to find a biomedical cure, and given a widely advocated, biopsychosocial understanding of non-specific low back pain management in the literature, it would be fruitful to investigate whether that mismatch of expectations in the initial consultation is currently recognised by GPs. Further, when the patient has a biomedical model of back pain and the health practitioner has a biopsychosocial model, how might that mismatch be best addressed in the initial consultation?

Finally, the role of GP "reassurance" about acute, non-specific low back pain merits investigation. Two aspects of GP reassurance may be considered. Firstly, messages that 'hurting does not equal

harming' and that staying active is advisable are potentially very important and should be given early (Coudeyre et al., 2007). Evidence suggests, however, that Step 1 reassurance fails to relieve back pain patients' worries (Moore et al., 2000). A better understanding of how such appropriate reassurance is delivered and received in consultation interactions could potentially contribute to improved outcomes. Step 1 reassurance may also relate to prognosis, however. In this regard, accumulating evidence indicates that reassuring patients that the prognosis for acute, non-specific low back pain is good may underplay many people's experiences of persistent, fluctuating and recurrent symptoms (Henschke et al., 2008). There is also evidence that patients stop consulting the GP before their back pain symptoms resolve; they may experience painful and disabling symptoms for a considerable period beyond stopping consulting (Burton et al., 2004; Croft et al., 1998). If and how these strands of evidence about prognosis reassurance are linked and their implications for back pain outcomes in the U.K. population warrant further research.

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